

**From:** Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]  
**Sent:** 4/14/2020 10:39:40 PM  
**To:** Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Bascles, Lionel [ (b) (6) Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron\_cohen]; Corey, Larry [ (b) (6) Desrosiers, Betsy [ (b) (6) Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickens]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [ (b) (6) Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaafe06ebd70-parkeras]; Payton, Manizhe (NIH/NIAID) [E] [ (b) (6) Resnansky, Laura [ (b) (6) Srinivasan, Badhri [ (b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike [ (b) (6) Wachtel, Jonathan [ (b) (6) ]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]  
**CC:** Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Jansen, Kathrin [ (b) (6) ]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [ (b) (6) Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [ (b) (6) Carluccio, Dana [ (b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina [ (b) (6) Heaton, Penny [ (b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [ (b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [ (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin [ (b) (6) Minnich, Beth [ (b) (6) Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Stratton, Benjamin [ (b) (6) Tolman, Brett [ (b) (6) Garner, Carlos [ (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Victoria Davey [ (b) (6) Hughes, Eric [er (b) (6) Hamilton, Nancy [ (b) (6) ]

**Subject:** ACTIV Clinical Trial Capacity Working Group - reporting meeting  
**Attachments:** Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment  
**Location:** [https://zoom.us/j/ \(b\) \(6\)](https://zoom.us/j/ (b) (6))  
**Start:** 4/21/2020 1:00:00 PM  
**End:** 4/21/2020 2:00:00 PM  
**Show Time As:** Busy

**Recurrence:** Weekly  
Occurs every Tuesday and Friday from 9:00 AM to 10:00 AM effective 4/21/2020 until 5/22/2020.  
**Required Attendees:** Bascles, Lionel; Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manzine; Resnansky, Laura; Srinivasan, Badhri; Stein, Peter (FDA/CDER); Vincent, Mike; Wachtel, Jonathan; Qashu, Felicia  
**Optional Attendees:** Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Carluccio, Dana; Cheryl (FNIH) Melencio [T] (b) (6) Francis Collins; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E] (b) (6) Stratton, Benjamin; Tolman, Brett; Garner, Carlos; Sizemore, Christine (NIH/FIC) [E]; Davey, Victoria; Jintanat Ananworanich

#### ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards,  
Karen

Karen H. Tountas, PhD  
Scientific Program Manager  
Foundation for the National Institutes of Health

Join Zoom Meeting  
[https://zoom.us/j/ \(b\) \(6\)](https://zoom.us/j/ (b) (6))

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US (New York)

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US (New York)  
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US (San Jose)

US (San Jose)

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Find your local number: <https://zoom.us/> (b) (6)



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**From:** Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]  
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**To:** Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]  
**CC:** Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]  
**Subject:** Moderna invitation  
**Attachments:** FNIH Covid 19 meeting April 03 2020 notes.docx  
  
**Flag:** Follow up

Hi Francis, for you to invite Stephane Bancel. We don't have time for the formality of a reply since the meeting is tomorrow AM at 9, so Mike will be reaching out to him right now with the logistics for the meeting on the assumption he will join.

---

**To:** (b) (6)  
**Subject:** URGENT: Invitation to join the ACTIV Vaccines Working Group

Dear Stephane,

As you know well, addressing the COVID-19 pandemic is an urgent priority for the entire biomedical research community. While the response has been broad and immediate, with many individuals and organizations already dedicated to applying their capabilities to respond, the field needs to find a way to focus and prioritize these many efforts, as there is of course still no proven treatment or vaccine.

NIH has been working at the forefront of addressing the crisis, including rapidly launching its own clinical trials of therapeutics and of course working with you at Moderna on accelerated testing of a vaccine candidate. In order to broaden the response we announced on Thursday a new public-private partnership with FDA, industry, and academic scientists to further accelerate progress against COVID and the threat of future pandemics, which we have decided to call Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV). As described in the attached meeting notes (from our kick-off on April 3) we have now set up Working Groups to decide efforts in four key areas—accelerating preclinical therapeutic development, optimizing clinical therapeutic development, coordinating clinical trials capacity, and supporting effective vaccine development.

I have heard and very much appreciate your interest in ACTIV. If you are amenable I would like to ask you if you would be willing to join as **a member on the Vaccines Working Group** which is being co-chaired by Doug Lowy of NCI and Kathrin Jansen of Pfizer. This group is charged with establishing a collaborative framework for advancing vaccine development. They are having just their second meeting tomorrow morning, so I expect there will still be plenty of areas of discussion that can benefit from your insights and expertise.

Please direct your response to this invitation to Mike Santos ( (b) (6) ) at FNIH, who will get to you immediately with the meeting logistics. I look forward to working with you on this critical effort.

Best,  
Francis

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**From:** Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]  
**Sent:** 7/24/2020 5:25:36 PM  
**To:** Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]  
**Subject:** FW: Summary of the ACTIV Immune Modulator Prioritization Adjudication and Confidentiality Forms  
**Attachments:** 2020-07-22\_TX-Immune\_Modulators\_Summary.pdf; Therapeutic Clinical Working Group Confidentiality Agreement Individual Template 5-28-2020.docx; Therapeutic Clinical Working Group Confidentiality Agreement Institution Template 5-28-2020.docx

Ellen,

An example of what is going out when we need agreements to review therapeutics.

Joe

---

**From:** Adam, Stacey (FNIH) [T] <(b) (6)>  
**Sent:** Friday, July 24, 2020 12:57 PM  
**To:** Chen, Helen Q. <(b) (6)> (b) (6) Fessel, Josh (NIH/NHLBI) [E]  
<(b) (6)> Deye, Greg (NIH/NIAID) [E] <(b) (6)> Punturieri, Antonello (NIH/NHLBI) [E]  
<(b) (6)> McNamara, James (NIH/NIAID) [E] <(b) (6)> Wung, Peter /US  
<(b) (6)> Vincent, Michael <(b) (6)> Goff, David (NIH/NHLBI) [E]  
<(b) (6)> Garner, Carl <(b) (6)> Robien, Mark (NIH/NIAID) [E]  
<(b) (6)> Toggias, Alkis (NIH/NIAID) [E] <(b) (6)> Patel, Naimish  
<(b) (6)> Gottesdiener, Keith <(b) (6)> Eric Hughes  
<(b) (6)> Aggarwal, Neil (NIH/NHLBI) [E] <(b) (6)> Levy, Elliot  
<(b) (6)> Rosenberg, Yves (NIH/NHLBI) [E] <(b) (6)> Buchman, Tim (OS/ASPR/BARDA)  
(CTR) <(b) (6)>  
**Cc:** Dana Carluccio <(b) (6)> Rose Li Central Account <(b) (6)>  
Read, Sarah (NIH/NIAID) [E] <(b) (6)> Young, John <(b) (6)> Colvis, Christine  
(NIH/NCATS) [E] <(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> Alvarez, Rosa Maria  
<(b) (6)>  
**Subject:** Summary of the ACTIV Immune Modulator Prioritization Adjudication and Confidentiality Forms

Dear Agent Prioritization Immune Modulator Subteam,

Please find attached the summary of our adjudication meeting on Wednesday. If you have any additions or amendments, please let us know.

In addition, based on our last cycle of reviews, the group expressed a desire to request more information for a few compounds that are requesting CDAs to release the data. In order to obtain this information, we will need to sign a CDA with this group to receive the information. Therefore, we will also need each of you (who is not a government employee) to sign a confidentiality agreement with us, so that we can then share the data with you.

Please find attached the template for the confidentiality agreements that we have been using for any of our ACTIV TX-Clinical WG members that needed to view confidential information. You will see that there are two versions of the confidentiality agreement.

- One version is for those individuals who are able to sign this type of agreement on your own behalf.
- One version is for those individuals whose institutions require that the institutional signatory sign on the individual's behalf.

We provide both options upfront as we may not which will apply to each of you.

Please review the confidentiality agreement and send back the signed copy as soon as you can. Once we have all of these signed and the information from the agent teams, we will circulate to the group for final review and decision on that agent. Please note, if you signed one of these for the Antiviral group, it will apply this one as well and you do not need to sign another.

Please return your signed agreement to Helen or myself as soon as you can. If you have any questions, do not hesitate to reach out.

Thanks,  
Stacey

Stacey J. Adam, PhD  
Director, Cancer  
Research Partnerships  
Foundation for the National Institutes of Health  
Direct: (b) (6) | Mobile: (b) (6)  
[fnih.org](http://fnih.org)  
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: [fnih.org/pandemic](http://fnih.org/pandemic)





**From:** (b) (6) | (b) (6)  
**Sent:** 7/14/2020 12:51:24 AM  
**To:** Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]  
**Subject:** Re: ACTIV Clinical Trial Capacity Working Group - reporting meeting  
**Attachments:** Clinical Trial Capacity Working Group Meeting Agenda\_07142020.pdf; ATT00001.htm

Hi Lauren,

I often have a conflict with this Clinical trial capacity WG meeting — are you free to join 9-10am tomorrow in listen mode? If so, could you take notes and track any information on the playbooks the WG will report tomorrow? We include information about this on the draft webpage and should be a useful update.

Thanks,  
Ashley

Begin forwarded message:

**From:** "Tountas, Karen (FNIH) [T]" <(b) (6)>  
**To:** "Bascles, Lionel" <(b) (6)>, "Cohen, Myron" <(b) (6)>, "Corey, Larry" <(b) (6)>, "Victoria Davey" <(b) (6)>  
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**Cc:** "Wachtel, Jonathan" <(b) (6)>, "Colvis, Christine (NIH/NCATS) [E]" <(b) (6)>  
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<(b) (6)>, "Mueller-Reichenstein, Petra" <(b) (6)>, "Pico, Dianna (NIH/NHLBI) [C]" <(b) (6)>  
"Quadros, Nora" <(b) (6)>, "Katz, Rebecca (NIH/NCATS) [E]" <(b) (6)>  
<(b) (6)>, "Hill, Zoe (NIH/NHLBI) [C]" <(b) (6)>, "Adam, Stacey (FNIH) [T]" <(b) (6)>, "Anderson, Margaret" <(b) (6)>  
"Parker, Ashley (NIH/OD) [E]" <(b) (6)>, "Carluccio, Dana" <(b) (6)>  
<(b) (6)>, "Culp, Michelle (NIH/OD) [E]" <(b) (6)>  
<michelle.cul <(b) (6)>, "Gadbois, Ellen (NIH/OD) [E]" <(b) (6)>  
"Gonzalez, Nina" <(b) (6)>, "Heaton, Penny" <(b) (6)>  
<(b) (6)>, "James, Stephanie (FNIH) [T]" <(b) (6)>, "Kenny,

Dermot" < (b) (6) "Kublin, James" < (b) (6) "Li, Rose"  
< (b) (6) "Menetski, Joseph (FNIH) [T]" < (b) (6) "Qashu,  
Felicia (NIH/OD) [E]" < (b) (6) "Santos, Michael (FNIH) [T]"  
< (b) (6) "Tuvevsson, Nancy" < (b) (6) "Wholley,  
David (FNIH) [T]" < (b) (6) "Elsaid, Olivia" < (b) (6)

**Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting**

Dear WG members; During this call we will share some exciting updates regarding the development of the 'playbooks'; and we will have an important discussion about updating the site survey for NCATS. Looking forward to the call and hope you can make it! Karen

Dear Clinical Trial Capacity Working group members - As the tiger teams continue to work closely with ACTIV protocol development and operations teams, and the 'playbook' development teams ramp up to quickly develop these resources, we will reduce the number of times the full WG meets in July to every other week (July 14th and 28th). Best, Karen

Karen Tountas is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

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**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

**Sent:** 4/30/2020 12:16:30 AM

**To:** Eric Hughes [ (b) (6) ]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [ (b) (6) ]; Mellors, John W [ /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [ (b) (6) ]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [ (b) (6) ]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [ (b) (6) ]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [ (b) (6) ]; Keith Gottesdiener [ (b) (6) ]; Elliott Levy [ (b) (6) ]; Wung, Peter /US [ (b) (6) ]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [ (b) (6) ]

**CC:** Elizabeth Kim [ (b) (6) ]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [ (b) (6) ]; Salathin, Carla [ (b) (6) ]; (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [ (b) (6) ]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]

**Subject:** ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5 (Materials)

**Attachments:** 2020-04-28\_TX\_Clinical\_WG\_Agent\_Prioritization\_Sub-WG\_Summary.pdf; ACTIV Therapeutics Clinical\_Agent Prioritization Sub-Group Meeting Agenda\_04302020.pdf

**Location:** <https://fnih.zoom.u> (b) (6)

**Start:** 4/30/2020 7:00:00 PM

**End:** 4/30/2020 8:00:00 PM

**Show Time As:** Tentative

**Required Attendees:** Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner

**Optional Attendees:** Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] (b) (6)

Dear TX-Clinical Agent Prioritization Subgroup,

Thank you all for all the hard work you all are doing right now for the agent scoring. I appreciate all the information sharing that has been happening today to allow others to see the compound information you have

found. I look forward chatting with you tomorrow to address any questions you may need addressed before our discussion of the results on Friday.

For reference tomorrow, please find attached the summary from yesterday's meeting and the agenda for tomorrow's meeting.

Thanks,

Stacey

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**From:** Marks, Peter [REDACTED] (b) (6)  
**Sent:** 5/16/2020 7:13:13 PM  
**To:** Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]  
**CC:** Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]  
**Subject:** RE: ChAdOx1

Dear Tony,

Will certainly include you next week on this call.

Best Regards,  
Peter

**From:** Fauci, Anthony (NIH/NIAID) [E] <[REDACTED]> (b) (6)  
**Sent:** Thursday, May 14, 2020 9:12 AM  
**To:** Marks, Peter <[REDACTED]> (b) (6); Mascola, John R (NIH) <[REDACTED]> (b) (6); Collins, Francis S (NIH) <[REDACTED]> (b) (6); Lane, Henry C (NIH) <[REDACTED]> (b) (6)  
**Cc:** Wholley, David N (NIH) <[REDACTED]> (b) (6); Tabak, Lawrence A (NIH) <[REDACTED]> (b) (6); Parker, Ashley S (NIH) <[REDACTED]> (b) (6)  
**Subject:** RE: ChAdOx1

I would also like to be on that call with the Pfizer CEO if we could possible arrange it.

Anthony S. Fauci, MD  
Director  
National Institute of Allergy and Infectious Diseases  
Building 31, Room 7A-03  
31 Center Drive, MSC 2520  
National Institutes of Health  
Bethesda, MD 20892-2520  
Phone: (301) [REDACTED] (b) (6)  
FAX: (301) 496-4409  
E-mail: [REDACTED] (b) (6)

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**From:** Marks, Peter (b) (6)  
**Sent:** Thursday, May 14, 2020 9:05 AM  
**To:** Mascola, John (NIH/VRC) [E] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6) Lane,  
Cliff (NIH/NIAID) [E] < (b) (6)>  
**Cc:** Fauci, Anthony (NIH/NIAID) [E] < (b) (6)> . Wholley, David (FNIH) [T] (b) (6); Tabak,  
Lawrence (NIH/OD) [E] (b) (6); Parker, Ashley (NIH/OD) [E] (< (b) (6)>)  
**Subject:** RE: ChAdOx1

Dear John,

Thanks for bringing the Pfizer issue up. I think that a call with their head of development and possibly also their CEO may be needed, and I wonder if Francis would like to join?

Best Regards,  
Peter

**From:** Mascola, John (NIH/VRC) [E] (b) (6)  
**Sent:** Thursday, May 14, 2020 9:03 AM  
**To:** Marks, Peter (b) (6); Collins, Francis S (NIH) (b) (6); Lane, Henry C (NIH) (b) (6)  
**Cc:** Fauci, Anthony S (NIH) < (b) (6)> Wholley, David N (NIH) < (b) (6)> Tabak, Lawrence A (NIH) < (b) (6)> , Parker, Ashley S (NIH) (b) (6) >  
**Subject:** RE: ChAdOx1

Francis - we did make good progress on ACTIV Vaccine WG. Yesterday on the vaccine clinical trials subgroup, we presented the harmonized protocol approach and high level details of phase 3 design. There was good input on both and general agreement, with some useful recommendations on efficient ways to conduct phase 3.

One issues is that the Pfizer representative on the subgroup, both Kathrin Jansen (who is co-chair of Vaccines WG), and Bill Gruber (Pfizer Senior VP for R&D) – took turns articulating their view that large Pharma companies like theirs prefer not to work with USG and it would just slow them down. When we asked for suggestions for DSMB, Kathrin said she did not agree that we should ask for nominations – because this issue required more discussion – mainly because Pfizer has no interest in this. Doug Lowy was on the call, so may be useful to get his perspective.

John

**From:** Marks, Peter < (b) (6)>  
**Sent:** Thursday, May 14, 2020 6:23 AM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6) >; Mascola, John (NIH/VRC) [E] (b) (6) >; Lane, Cliff (NIH/NIAID) [E] < (b) (6)>  
**Cc:** Fauci, Anthony (NIH/NIAID) [E] < (b) (6)> >; Wholley, David (FNIH) [T] (b) (6) > Tabak, Lawrence (NIH/OD) [E] < (b) (6)> Parker, Ashley (NIH/OD) [E] (b) (6) >  
**Subject:** RE: ChAdOx1

Dear Francis,

We had made good progress with the Oxford AZ team on the clinical end before the contracting period began. From my last conversation with the AZ clinical team they were on board with the USG concept of a large phase 3 trial, potentially as part of a master protocol if the timing was right. Their major issue was getting moving rapidly.

Among other things, Tony, John and I discussed the concept that  
(b) (5)

(b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

Happy to discuss

further.

Best Regards,  
Peter

**From:** Collins, Francis (NIH/OD) [E] < (b) (6) >

**Sent:** Thursday, May 14, 2020 5:38 AM

**To:** Mascola, John R (NIH) < (b) (6) >; Lane, Henry C (NIH) < (b) (6) >; Marks, Peter < (b) (6) >

**Cc:** Fauci, Anthony S (NIH) < (b) (6) >; Wholley, David N (NIH) < (b) (6) >; Tabak, Lawrence A (NIH) < (b) (6) >; Parker, Ashley S (NIH) < (b) (6) >

**Subject:** ChAdOx1

Gentlemen:

I need to know the update on where we are with Oxford, A-Z, and ChAdOx1. I see there's a BARDA WebEx at 5 pm, and I have a rescheduled phone call this morning with John Bell. I'd like to be as useful as possible in making a plan that includes this vaccine program as part of the harmonized master protocol. Advice about how to use the call with John Bell most effectively would be most welcome!

And did the Vaccines WG make good progress yesterday on the details of the harmonized master protocol? Did they agree in principle to a single DSMB?

Thanks, Francis

**From:** Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415B886087D08B628E6F-ME\_LENCIOC]  
**Sent:** 7/22/2020 3:37:35 PM  
**To:** Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Do sten, Mikael [ (b) (6) ]; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Pao, William [ (b) (6) ]; Plump, Andrew [ (b) (6) ]; Stoffels, Paul [ (b) (6) ]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Corvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [ (b) (6) ]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [ (b) (6) ]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [ (b) (6) ]  
**CC:** Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [ (b) (6) ]; Anderson, Margaret [ (b) (6) ]; Chen, Helen [ (b) (6) ]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0fa7bd]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Stratton, Ben [ (b) (6) ]; Tolman, Brett [ (b) (6) ]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [ (b) (6) ]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabca2247548e596778304f781f-austinc]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Castillejos, Carlos [ (b) (6) ]; Culp, Michele (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; FNIH Central Account [ (b) (6) ]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisei]; Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group



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 (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 [ (b) (6) Protasiewicz, Ann [ (b) (6) Riccobene, Kim  
 [ (b) (6) m]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen  
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 [ (b) (6) Zottoli, Jessica [ (b) (6)

**Subject:** ACTIV EC & Working Group Co-Chair Meeting

**Location:** <https://fnih.zoom.us/> (b) (6)

**Start:** 8/14/2020 4:00:00 PM

**End:** 8/14/2020 5:30:00 PM

**Show Time As:** Tentative

**Required Attendees:** Collins, Francis (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Marks, Peter (FDA/CBER); Pao, William; Plump, Andrew; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy, Hughes, Eric, Jansen, Kathryn; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John

**Optional Attendees:** Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Toiman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Anderson, James (NIH/OD) [E]; Austin, Christopher

(NIH/NCATS) [E]; Burklow, John (NIH/OD) [E]; Castillejos, Carlos; Culp, Michelle (NIH/OD) [E]; FNIH Central Account; Gadbois, El en (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Myles, Renate (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hardesty, Rebecca (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Gorman, Greta (FNIH) [T]; Meitzer, Abbey (FNIH) [T]; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
**Sent:** 4/17/2020 7:48:38 PM  
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**CC:** Mary Biggs | (b) (6) Demarcus | (b) (6) Macone, Erin | (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan | (b) (6) Elizabeth Kim | (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Rose Li Central Account | (b) (6) Lucas Smalldon | (b) (6) Butcher, Tina | (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wung, Peter /US | (b) (6)

**Subject:** ACTIV TX-Clinical Master Protocol Subgroup Meeting #4

**Location:** <https://fnih.zoom.us> (b) (6)

**Start:** 4/21/2020 5:00:00 PM

**End:** 4/21/2020 6:00:00 PM

**Show Time As:** Tentative

**Required Attendees:** Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylvia (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER)

**Optional Attendees:** Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Rose Li Central Account; Lucas Smalldon; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Wung, Peter /US



Dear TX-Clinical Master Protocol Subgroup,

This will be our 3<sup>rd</sup> meeting. We will update with materials after the weekend and Monday's call.

Thanks,

Stacey

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(b) (6) (b) (6) (b) (6) (b) (6) Haynes, Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002.mc]; (b) (6)  
(b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) | (b) (6) Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb9cc56fdb4598a57b423d484dcf9f-offit email];  
(b) (6) Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccb4e3caaf5eb5d3586b1cc-Jonathan.Se];  
(b) (6) Tal Zaks | (b) (6) (b) (6)  
(b) (6) (b) (6) Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron\_cohen]; Denny, Joshua (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb4626dabbb45aa8b8e5d21169344e6-dennyjc]; (b) (6) ;  
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(b) (6) (b) (6) Ledgerwood, Julie (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5dc9f31ded594eff8ac506d2c4103c15-ledgerwood]; Mleyssen@its.jnj.com;  
Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Marovich, Mary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfd0192d165d4643accf6347728dbaeb-marovichma]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola];  
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(b) (6) Laurent Humeau | (b) (6) Schrag, Stephanie (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9be29b344ba14363bdecaa43582ca226-ZHA6]; Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c249692151d46d6ac80cb28ada3d3a0-qzr7]; Hotez, Peter Jay |  
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(b) (6) (b) (6) (b) (6) Greg Glenn | (b) (6)  
**CC:** Tolman, Brett | (b) (6) (b) (6) Hopps, Markay | (b) (6)  
Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group

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(b) (6) Jeneffer Haynes (b) (6) (b) (6)

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(b) (6) Isabel Ramsey | (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijs]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy | (b) (6) Hughes, Eric | (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John (b) (6) Hamilton, Holli (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a28fc2f8eb134b00b5eaa4222d0576cc-Holli.Hamil]; Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.com]; Schrag, Stephanie (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9be29b344ba14363bdecaa43582ca226-ZHA6]; Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c249692151d46d6ac80cb28ada3d3a0-qzr7]; Thornburg, Natalie (CDC/DDID/NCIRD/DVD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d079e00a5649639c6f1425f3bb075f-nax3]; Paul Gillard | (b) (6) Brian Rosen | (b) (6) Cheryl Keech | (b) (6) (b) (6) Bethany Stokes | (b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; 'Wachtel, Jonathan' (b) (6) Stratton, Benjamin | (b) (6) Anderson, Margaret | (b) (6) |

**Subject:** Agenda for ACTIV Vaccines Working Group meeting: Tomorrow, 28 May

Dear Vaccines Working Group and Vaccines Clinical Trials Sub-Group members,

The agenda for **Vaccines Working Group meeting** tomorrow (Thursday) at 2pm ET (11am PT / 8pm CEST) is:

- Matt Biggerstaff, from CDC's modeling team, will present on predictive modeling of incidence to inform vaccine efficacy trials
- Time permitting, we will discuss updates from the Sub-Groups

Given the importance of the first agenda item to the Vaccines Clinical Trials Sub-Group, we are inviting that group to join the meeting. The calendar invite follows this note. As a reminder, we have two meetings scheduled tomorrow, and many of you will also receive an email about the Vaccines Clinical Trials Sub-Group meeting (at 11am ET).

We also want to provide a preview of a coming set of requests: As we have previously discussed, NIAID is constituting a DSMB for the efficacy trials that are implemented with US government funding. The Vaccines Clinical Trials Sub-Group was asked for DSMB member recommendations: thanks to those who sent input. We will be sharing a list of potential DSMB members from NIAID with the Vaccines Clinical Trials Sub-Group (cc'ing the Working Group) today for feedback. Based on that feedback, NIAID will propose a list of members and alternates. We will circulate that list to the Vaccines Working Group (cc'ing the Sub-Group) for final input before NIAID finalizes the list and reaches out to proposed members. We apologize in advance for the short turn-around times that will be requested given the necessity of finalizing the DSMB members in time for an early July trial start.

We're looking forward to the meeting tomorrow. Please feel free to reach out with any questions or suggestions.

Best regards,  
Brett and Mike

Michael Santos, PhD  
Associate Vice President, Science  
Foundation for the National Institutes of Health  
(b) (6) [fnih.org](https://fnih.org)  
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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**CC:** Barasch, Kimberly (NIH/NIAID) [C] [ (b) (6) Conrad, Patricia (NIH/NIAID) [E] [ (b) (6) Dimishkov, Roxanne (NIH/NHLBI) [C] [ (b) (6) McManus, Ayanna (NIH/OD) [E] [ (b) (6) Protasiewicz, Ann [ (b) (6) Thomas, Ashley (FDA/CDER) [ (b) (6) Wood, Gretchen (NIH/OD) [E] [ (b) (6) Zanellato, Ann [AZanell2@its.jnj.com]; Zottoli, Jessica [ (b) (6) Togashi, Mieko (NIH/NC) [E] [ (b) (6) Sepulveda, Dorina (FNIH) [T] [ (b) (6) Lagos, Enrique (NIH/NCATS) [E] [ (b) (6) Simon, Dina (NIH/OD) [C] [ (b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [ (b) (6) Hardesty, Rebecca (NIH/OD) [C] [ (b) (6) Alvarez, Rosa [ (b) (6) Anderson, Margaret [ (b) (6) Elsaid, Olivia [ (b) (6) Gonzalez, Nina [ (b) (6) Kim, Elizabeth [ (b) (6) Stratton, Ben [ (b) (6) Tolman, Brett [ (b) (6) ]; Wachtel, Jonathan [ (b) (6)

**Subject:** ACTIV mtg with Exec Comm and WG co-chairs

**Location:** <https://nih.zoom.us>, (b) (6)

**Start:** 5/13/2020 12:00:00 PM

**End:** 5/13/2020 1:00:00 PM

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**Required Attendees:** Collins, Francis (NIH/OD) [E]; Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Pao, William; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Wholley, David (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Freire, Maria (FNIH) [T]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Wolinetz, Carrie (NIH/OD) [E]  
**Optional Attendees:** Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Protasiewicz, Ann; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Zanellato, Ann; Zottoli, Jessica; Togashi, Mieko (NIH/NCI) [E]; Sepulveda, Dorina (FNIH) [T]; Lagos, Enrique (NIH/NCATS) [E]; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Hardesty, Rebecca (NIH/OD) [C]; Alvarez, Rosa; Anderson, Margaret; Elsaid, Olivia; Gonzalez, Nina; Kim, Elizabeth; Stratton, Ben; Tolman, Brett; Wachtel, Jonathan

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**From:** Gadbois, El en (N H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]  
**Sent:** 5/21/2020 8:01:27 PM  
**To:** Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]  
**Subject:** FW: Slides for ACTIV TX-Clinical Working Group Meeting #7  
**Attachments:** ACTIV Therapeutics-Clinical Full Working Group 21May2020 Meeting Guide.pdf

Did you get this in time to join today? I did. You should try to follow this group. They mostly talked about their plans for a master protocol for the mAbs and I'm sure you would get more out of the details. But I have some observations (not urgent to discuss).

**From:** Adam, Stacey (FNIH) [T] < (b) (6) >  
**Sent:** Thursday, May 21, 2020 12:44 PM  
**To:** Bozzette, Sam (NIH/NCATS) [E] < (b) (6) > Butterson, Joan < (b) (6) > De Claro, R. Angelo (FDA/CDER) < (b) (6) > Draghia-Akli, Ruxandra < (b) (6) > Eisner, Mark < (b) (6) > Gottesdiener, Keith < (b) (6) > Hughes, Eric < (b) (6) > Judy Currier < (b) (6) > Kim, Elizabeth < (b) (6) > LaVange, Lisa < (b) (6) > Levy, Elliot < (b) (6) > Mellors, John W < (b) (6) > Menon, Sandeep < (b) (6) > Parker, Ashley (NIH/OD) [E] < (b) (6) > Patel, Naimish < (b) (6) > Peppercorn, Amanda < (b) (6) > Poole, Mike < (b) (6) > Proschan, Michael (NIH/NIAID) [E] < (b) (6) > Read, Sarah (NIH/NIAID) [E] < (b) (6) > Santos, Michael (FNIH) [T] < (b) (6) > Shen, Yuan Li (FDA/CDER) < (b) (6) > Stein, Peter (FDA/CDER) < (b) (6) > Wholley, David (FNIH) [T] < (b) (6) > Buchman, Tim (OS/ASPR/BARDA) (CTR) < (b) (6) > Collins, Sylva (FDA/CDER) < (b) (6) > Amanda Peppercorn < (b) (6) > Garner, Carl < (b) (6) > Higgs, Elizabeth (NIH/NIAID) [E] < (b) (6) > Koroshetz, Walter (NIH/NINDS) [E] < (b) (6) > Burgess, Timothy < (b) (6) > Reineck, Lora (NIH/NHLBI) [E] < (b) (6) > Aggarwal, Neil (NIH/NHLBI) [E] < (b) (6) > Rosenberg, Yves (NIH/NHLBI) [E] < (b) (6) > Brown, Jeremy (NIH/NINDS) [E] < (b) (6) > Gadbois, El en (NIH/OD) [E] < (b) (6) >  
**Cc:** Colvis, Christine (NIH/NCATS) [E] < (b) (6) > Desrosiers, Betsy < (b) (6) > Jansen, Kathrin < (b) (6) > Kurilla, Michael (NIH/NCATS) [E] < (b) (6) > Lowy, Douglas (NCI) < (b) (6) > Young, John < (b) (6) > Biggs, Mary < (b) (6) > Butcher, Tina < (b) (6) > Demarcus < (b) (6) > Macone, Erin < (b) (6) > Melencio, Cheryl (FNIH) [T] < (b) (6) > Salathin, Carla < (b) (6) > Tountas, Karen (FNIH) [T] < (b) (6) > Menetski, Joseph (FNIH) [T] < (b) (6) > James, Stephanie (FNIH) [T] < (b) (6) > Wachtel, Jonathan < (b) (6) > Tolman, Brett < (b) (6) > Alvarez, Rosa < (b) (6) > Gonzalez, Nina < (b) (6) > Dana Carluccio < (b) (6) > Rose LI Central Account < (b) (6) > Anderson, Margaret < (b) (6) > Lucas Sma Idon < (b) (6) > Stratton, Benjamin < (b) (6) > Mollica, Linda /US < (b) (6) > Qashu, Felicia (NIH/OD) [E] < (b) (6) > Patterson, Amy (NIH/NHLBI) [E] < (b) (6) > Goff, David (NIH/NHLBI) [E] < (b) (6) > Rubin, Daniel B. (FDA/CDER) < (b) (6) >  
**Subject:** Slides for ACTIV TX-Clinical Working Group Meeting #7

Dear ACTIV TX Clinical WG,

Looking forward to seeing you all soon at the meeting. Please find attached the slides for the meeting.

Thanks,  
Stacey

Stacey J. Adam, PhD  
Director, Cancer  
Research Partnerships

Direct: (b) (6) | Mobile: (b) (6)

Join Zoom Meeting

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From: Melencio, Cheryl (FNIH) [T] [/o=EXCHangelABS/ou=EXCHange ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=279E14FA7428415BB86087D08B628E6F-ME.LENCIOC]  
Sent: 1/12/2021 10:03:02 PM  
To: Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Bancel, Stephane [ (b) (6) Carter, Kara [ (b) (6) Cavaleri, Marco [ (b) (6) Cihlar, Tomas [ (b) (6) ]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [ (b) (6) Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Victoria Davey [ (b) (6) Dsbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Do sten, Mikael [ (b) (6) Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Erck, Stan [ (b) (6) ]; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Hudson, Thomas [ (b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn [ (b) (6) ]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Lepore, John [john.j. (b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Meeker, David [ (b) (6) ]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NARS]; Pandya, Hitesh [ (b) (6) Pangalos, Mene [ (b) (6) Pao, William [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Paul, Steve [ (b) (6) Perlmutter, Roger [ (b) (6) ]; Plenge, Robert [ (b) (6) Plump, Andy [ (b) (6) Rachel Ramoni [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d3f6cb5237a44b75887b8a1ca1f9bb91-Rachel.Ramo]; Reed, John [ (b) (6) Reese, David [ (b) (6) Rouse, Doris [ (b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel [ (b) (6) ]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul [ (b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Tal ey, Michael [ (b) (6) Tsai, John [ (b) (6) Vessey, Rupert [ (b) (6) Virgin, Skip [ (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John [ (b) (6) ]

(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis], Desrosiers, Betsy  
 | (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes], Jansen, Kathrin  
 | (b) (6) ]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI)  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID)  
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Anderson, James (NIH/OD)  
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Burklow, John  
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Carluccio, Dana  
 | (b) (6) Castilejos, Carlos | (b) (6) ]; FNIH Central Account  
 | (b) (6) Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dof75b31b-halletta]; Lumsden, Joanne  
 (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; Myles, Renate (NIH/OD)  
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wolnetz, Carrie (NIH/OD)  
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolnetzcd]; Adam, Stacey (FNIH) [T]  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Margaret Anderson  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Appell, Evan  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Chen, Helen  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Connelly, Sarah  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; Gonzalez, Nina  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Hawk, Harrison  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mendelson, Jesse  
 (b) (6) Nasr, Hana [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userfe0939a1]; Sorosa, Alex  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact\_f12]; Stratton,  
 Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188]; bto man  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan (b) (6) Meltzer,  
 Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]  
 CC: Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; Barasch, Kimberly  
 (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Bell, Julie  
 (b) (6) ]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Carver, Trea (NIH) [C]  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Caulfield, Anita  
 | (b) (6) Coan, Amanda | (b) (6) Conrad, Patricia (NIH/NIAID) [E]  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne  
 (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Edl, Susan  
 | (b) (6) Fuhrer, Nicole | (b) (6) Giorgi, Sara | (b) (6)  
 Hoban, Michele | (b) (6) Hoffstetter, Renata (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e9758570bf4ca08552ea377170ec2a-hoffstetter];

Iberdemaj, Vaide | (b) (6) Jenkins, Christine S. | (b) (6) m], Krack, Kimberly [kimberly]; (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Lever, Susan | (b) (6) Magbie-Robinson, Kim (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=74a5b9cea10b4f919d9db20c8aaec3e7-magbierobin]; Martin, Melissa | (b) (6) McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Minnich, Beth | (b) (6) Peralá, Mie | (b) (6) Protasiewicz, Ann | (b) (6) Riccobene, Kim | (b) (6) Riffin, Mary | (b) (6) Ripley, Nadege | (b) (6) Schuster, Donna | (b) (6) Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Suhana, Tina (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07e062bf05a14748ba3d9fbb3e468057-esuhana]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Togash, Mieko (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togashm]; Underwood, Nancy | (b) (6) Zottoli, Jessica | (b) (6) Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugneskp]; Magbie-Robinson, Kim (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=74a5b9cea10b4f919d9db20c8aaec3e7-magbierobin]

**Subject:** ACTIV Leadership Team Call #17

**Location:** <https://fnih.zoom.us/> (b) (6)

**Start:** 6/28/2021 12:00:00 PM

**End:** 6/28/2021 1:30:00 PM

**Show Time As:** Tentative

**Required Attendees:** Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Davey, Victoria; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER), Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathryn; Kurla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Lumsden, Joanne (NIH/NCATS) [C]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Appell, Evan; Chen, Helen; Connelly, Sarah; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Nasr, Hana; Sorosa, Alex; Stratton, Ben; Tolman, Brett; Wachtel, Jonathan; Meltzer, Abbey (FNIH) [T]

**Optional Attendees:** Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Caulfield, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lagos, Enrique (NIH/NCATS) [E]; Lever, Susan; Magbie-Robinson, Kim (NIH/OD) [C]; Martin, Melissa; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Peralá, Mie; Protasiewicz, Ann; Riccobene, Kim;

Riggin, Mary; Ripley, Nadege; Schuster, Donna; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, T na (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoi, Jessica; Hughes, Karen (NIH/OD) [E]; Magbie-Robinson, Kim

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Italy  
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Passcode: (b) (6)

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**From:** Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415B886087D08B628E6F-ME.LENCIOC]  
**Sent:** 12/15/2020 5:35:53 PM  
**To:** Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Austin, Christopher (NIH/NCATS) [E] [ (b) (6) Carter, Kara [ (b) (6) Cavaleri, Marco [ (b) (6) Cihlar, Tomas [ (b) (6) ]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [ (b) (6) Culp, Michelle (NIH/OD) [E] [ (b) (6) Victoria Davey [ (b) (6) Disbrow, Gary (OS/ASPR/BARDA) [ (b) (6) Dolsten, Mikael [ (b) (6) Erbeling, Emily (NIH/NIAID) [E] [ (b) (6) Erck, Stan [ (b) (6) Gadbois, Ellen (NIH/OD) [E] [ (b) (6) Gibbons, Gary (NIH/NHLBI) [E] [ (b) (6) Hudson, Thomas [ (b) (6) James, Stephanie (FNIH) [T] [ (b) (6) Johnson, Robert (OS/ASPR/BARDA) [ (b) (6) Kramer, Lynn [ (b) (6) ]; Lane, Cliff (NIH/NIAID) [E] [ (b) (6) Marks, Peter (FDA/CBER) [ (b) (6) ]; Marston, Hilary (NIH/NIAID) [E] [ (b) (6) Mascola, John (NIH/VRC) [E] [ (b) (6) Meeker, David [ (b) (6) Menetski, Joseph (FNIH) [T] [ (b) (6) Messonnier, Nancy (CDC/DDID/NCIRD/OD) [ (b) (6) Pandya, Hitesh [ (b) (6) Pao, William [ (b) (6) Parker, Ashley (NIH/OD) [E] [ (b) (6) Perlmutter, Roger [ (b) (6) Plenge, Robert [ (b) (6) Plump, Andy [ (b) (6) Rouse, Doris [ (b) (6) Santos, Michael (FNIH) [T] [ (b) (6) Skovronsky, Daniel [ (b) (6) Stein, Peter (FDA/CDER) [ (b) (6) Tabak, Lawrence (NIH/OD) [E] [ (b) (6) Talley, Michael [ (b) (6) Tsai, John [ (b) (6) Vessey, Rupert [ (b) (6) Virgin, Skip [ (b) (6) Wholley, David (FNIH) [T] [ (b) (6) Woodcock, Janet (FDA/CDER) [ (b) (6) Young, John [ (b) (6) Colvis, Christine (NIH/NCATS) [E] [ (b) (6) Eric Hughes [ (b) (6) Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [ (b) (6) Lowy, Douglas (NCI) [ (b) (6) Read, Sarah (NIH/NIAID) [E] [ (b) (6) Adam, Stacey (FNIH) [T] [ (b) (6) Margaret Anderson [ (b) (6) Appell, Evan [ (b) (6) Chen, Helen Q. [ (b) (6) ]; Connelly, Sarah [ (b) (6) ]; Gonzalez, Nina [ (b) (6) Hawk, Harrison [ (b) (6) Mendelson, Jesse [ (b) (6) Nasr, Hana [ (b) (6) ]; Sorosa, Alex David [ (b) (6) Stratton, Benjamin [ (b) (6) btolman [ (b) (6) ]; Tountas, Karen (FNIH) [T] [ (b) (6) Wachtel, Jonathan [ (b) (6) Anderson, James (NIH/OD) [E] [ (b) (6) ]; Burklow, John (NIH/OD) [E] [ (b) (6) Carluccio, Dana [ (b) (6) Castillejos, Carlos [ (b) (6) FNIH Central Account [ (b) (6) Hallett, Adrienne (NIH/OD) [E] [ (b) (6) Myles, Renate (NIH/OD) [E] [ (b) (6) Wolinetz, Carrie (NIH/OD) [E] [ (b) (6) Meltzer, Abbey (FNIH) [T] [ (b) (6) Esser, Mark [ (b) (6) Bancel, Stephane [ (b) (6) ]; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Lepore, John [ (b) (6) Pangalos, Mene [ (b) (6) Paul, Steve [ (b) (6) Rachel Ramoni [ (b) (6) Reed, John [ (b) (6) ]; Reese, David [ (b) (6) Stoffels, Paul [ (b) (6) Desrosiers, Betsy [ (b) (6) CC: Austin, Sarah (NIH/NIAID) [E] [ (b) (6) Barasch, Kimberly (NIH/NIAID) [C] [ (b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [ (b) (6) Carver, Trea (NIH) [C] [ (b) (6) ]; Caulfied, Anita [ (b) (6) Coan, Amanda [ (b) (6) ]; Conrad, Patricia (NIH/NIAID) [E] [ (b) (6) Dimishkov, Roxanne (NIH/NHLBI) [C] [ (b) (6) Edl, Susan [ (b) (6) ]; Fuhrer, Nicole [ (b) (6) Giorgi, Sara [ (b) (6) Hoffstetter, Renata (FNIH) [T] [ (b) (6) Ilerdemaj Varde [ (b) (6) Jenkins, Christine S. [ (b) (6) Lagos, Enrique (NIH/NCATS) [E] [ (b) (6) Lever, Susan [ (b) (6) Martin, Melisa [ (b) (6) McManus, Ayanna (NIH/OD) [E] [ (b) (6) Minnich, Beth [ (b) (6) Perala, Mie [ (b) (6) Protasiewicz, Ann [ (b) (6) Riccobene, Kim [ (b) (6) m]; Riffin, Mary [ (b) (6) Ripley, Nadege [ (b) (6)

Schuster, Donna [ (b) (6)	Sepulveda, Dorina (FNIH) [T] [ (b) (6)	Simon, Dina
(NIH/OD) [C] [ (b) (6)	Suhana, Tina (NIH/VRC) [E] [ (b) (6)	Thomas, Ashley
(FDA/CDER) [ (b) (6)	Wood, Gretchen (NIH/OD) [E] [ (b) (6)	Togashi, Mieko
(NIH/NCI) [E] [ (b) (6)	Underwood, Nancy [ (b) (6)	Zottoli, Jessica
[ (b) (6)	Hughes, Karen (NIH/OD) [E] [ (b) (6)	Tajalli, Ada (NIH/OD) [E]
[ (b) (6)	Regan, Donna M [ (b) (6)	Magbie-Robinson, Kim (NIH/OD) [C]
[ (b) (6)	Vessey, Rupert [ (b) (6)	Lowy, Douglas (NIH/NCI) [E]
[ (b) (6)	Lumsden, Joanne (NIH/NCATS) [C] [ (b) (6)	Ellis, Carol
[ (b) (6)	Bell, Julie [ (b) (6)	Hoban, Michelle [ (b) (6)

**Subject:** \*ACTIV Leadership/EC Call #12

**Attachments:** 01.14 ACTIV EC and Leadersh.p Team Meeting 20210113 vF2.pdf; 01.14 ACTIV EC and Leadership Team Meeting\_APPENDIX 20210113 vF.pdf; 2020-12-16 ACTIV Leadership Team and Executive Committee Meeting\_Summary vF.docx, 2021-01-14 ACTIV Leadership Team and Executive Committee Meeting\_Summary vF.pdf

**Location:** <https://fnih.zoom.us/> (b) (6)

**Start:** 1/14/2021 3:30:00 PM

**End:** 1/14/2021 5:00:00 PM

**Show Time As:** Busy

**Required Attendees:** Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry, Culp, Michelle (NIH/OD) [E]; Davey, Victoria; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson Robert (OS/ASPR/BARDA), Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michae (NIH/NCATS) [E]; Lowy, Doug as (NCI), Read, Sarah (NIH/NIAID) [E]; Adam, Stacey (FNIH) [T]; Anderson, Margaret, Appell, Evan; Chen, Helen; Connelly, Sarah; Gonzalez, Nina, Hawk, Harrison; Mendelson, Jesse; Nasr, Hana; Sorosa, Alex, Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Meltzer, Abbey (FNIH) [T]; Esser, Mark

**Optional Attendees:** Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Caulfield, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara, Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Idermaj, Vaide, Jenkins, Christine S.; Krack, Kimberly, Lagos, Enrique (NIH/NCATS) [E]; Lever, Susan, Martin, Melisa; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth, Perala, Mie, Protasiewicz, Ann; Riccobene, Kim; Rigglin, Mary; Ripley, Nadege; Schuster, Donna, Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Hughes, Karen (NIH/OD) [E]; Tajalli, Ada (NIH/OD) [E]; Regan, Donna M; Magbie-Robinson, Kim; Vessey, Rupert; Lowy, Douglas (NIH/NCI) [E]; Lumsden, Joanne (NIH/NCATS) [C]; Ellis, Carol

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**From:** Cat Lutz [ (b) (6) ]  
**Sent:** 10/28/2020 12:57:08 PM  
**To:** Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6)  
(b) (6) ; (b) (6) ; (b) (6) ; (b) (6)  
(b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];  
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];  
(b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras];  
Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];  
(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [ (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [ (b) (6) ]; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [ (b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6)  
**CC:** Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [ (b) (6) ]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim, Elizabeth [ (b) (6) ] btoiman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan [ (b) (6) ]; Prabhavathi



Fernandes | (b) (6) Diamond, Michael | (b) (6) Rose Li  
| (b) (6) Dana Carluccio | (b) (6) Lagos, Enrique (NIH/NCATS)  
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Jonson, Samantha  
(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];  
Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi  
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D  
| (b) (6) Dave Frankowski | (b) (6) Baric, Toni C  
| (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative  
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint  
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoonoh]; Stratton, Benjamin  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188];  
Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James  
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]

**Subject:** RE: ACTIV Preclinical full working group

Interesting paper on the S614G variant:

<https://www.biorxiv.org/content/10.1101/2020.10.27.357558v1>

Cathleen Lutz, Ph.D. MBA

Senior Director, Mouse Repository & In Vivo Pharmacology  
Rare and Orphan Disease Center

(b) (6)

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-----Original Appointment-----

**From:** Menetski, Joseph (FNIH) [T] <(b) (6)>

**Sent:** Tuesday, April 14, 2020 6:43 PM

**To:** Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E];

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Baric, Ralph;

(b) (6)

Ottinger, Elizabeth (NIH/NCATS

[E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER);

(b) (6)

Cat Lutz;

(b) (6)

Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD)

[E]; ken.duncan@gatesfoundation.org, Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E];

Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette,

Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E];

(b) (6)

**Cc:** Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy;

Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E];

Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa

Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana

Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C];

Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski, Baric, Toni C; Lowy, Douglas (NIH/NCI) [E];

GADB0000002087-2517698

Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]

**Subject:** [EXTERNAL]ACTIV Preclinical full working group

**When:** Wednesday, October 28, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

**Where:** <https://fnih.zoom.us/> (b) (6)

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**Sent:** 9/11/2020 6:23:28 PM  
**Subject:** FW: Notes from Wednesday's ACTIV Executive Committee and Co-chair Meeting  
**Attachments:** 2020-09-09\_Executive\_Committee\_Meeting\_Summary\_FINAL.docx

**From:** Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]  
**Sent:** Friday, September 11, 2020 1:52 PM  
**To:** Collins, Francis (NIH/OD) [E] <(b) (6)> Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)>  
Dolsten, Mikael <(b) (6)> Fauci, Anthony (NIH/NIAID) [E] <(b) (6)> Gibbons, Gary  
(NIH/NHLBI) [E] <(b) (6)> Marks, Peter (FDA/CBER) <(b) (6)> Pao, William  
<(b) (6)> Plump, Andrew <(b) (6)> Stoffels, Paul <(b) (6)>  
Woodcock, Janet (FDA/CDER) <(b) (6)> Colvis, Christine (NIH/NCATS) [E]  
<(b) (6)> Desrosiers, Betsy <(b) (6)> Eric Hughes  
<(b) (6)> Jansen, Kathrin <(b) (6)> Kurilla, Michael (NIH/NCATS) [E]  
<(b) (6)> Lowy, Douglas (NCI) <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)>  
Young, John <(b) (6)>  
**Cc:** Adam, Stacey (FNIH) [T] <(b) (6)> Alvarez, Rosa Maria <(b) (6)> Margaret Anderson  
<(b) (6)> Appell, Evan <(b) (6)> Chen, Helen Q. <(b) (6)>  
Elsaid, Olivia <(b) (6)> Gonzalez, Nina <(b) (6)> Hawk, Harrison  
<(b) (6)> Mendelson, Jesse <(b) (6)> Menetski, Joseph (FNIH) [T]  
<(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Stratton, Benjamin <(b) (6)>  
btolman <(b) (6)> Tountas, Karen (FNIH) [T] <(b) (6)> Wachtel, Jonathan  
<(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Anderson, James (NIH/OD) [E]  
<(b) (6)> Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Burklow, John (NIH/OD) [E]  
<(b) (6)> Castillejos, Carlos <(b) (6)> Culp, Michelle (NIH/OD) [E]  
<(b) (6)> FNIH Central Account <(b) (6)> Freire, Maria (FNIH) [T]  
<(b) (6)> Gadbois, Ellen (NIH/OD) [E] <(b) (6)> Hallett, Adrienne (NIH/OD) [E]  
<(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Myles, Renate (NIH/OD) [E]  
<(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Tabak, Lawrence (NIH/OD) [E]  
<(b) (6)> Wolinetz, Carrie (NIH/OD) [E] <(b) (6)> Burklow, John (NIH/OD) [E]  
<(b) (6)> Gorman, Greta (FNIH) [T] <(b) (6)> Meltzer, Abbey (FNIH) [T]  
<(b) (6)>

**Subject:** Notes from Wednesday's ACTIV Executive Committee and Co-chair Meeting

Dear All:

Please see the notes from our teleconference on Wednesday, September 9. The action items are listed at the top of the document. Please let me know any additional comments or questions regarding these notes.

Thank you again for all your support of and contributions to ACTIV

Regards,

David

David Wholley  
Senior Vice-President, Research Partnerships  
Foundation for the National Institutes of Health  
(b) (6)

fnih.org

11400 Rockville Pike Suite 600 North Bethesda MD 20852

*In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.*

**From:** Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]

**Sent:** 6/7/2020 3:22:30 PM

**To:** (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; (b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan]; Beth Bell (b) (6) (b) (6) (b) (6) Cavaleri Marco (b) (6) (b) (6) (b) (6) Greg Glenn (b) (6) (b) (6) Haynes, Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002.mc]; (b) (6) (b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Nelson Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c3323ab6a02468689fa2c51a87c43cc-NelsonMicha]; Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb9cc56f8be4598a57b423d484dcf9f-offit.email]; HSchuite@rts.jnj.com; Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccb4e3caaf5eb5d3586b1cc-Jonathan.Se]; (b) (6) Tal Zaks (b) (6) (b) (6) (b) (6) Hopps, Markay (b) (6) (b) (6) Tolman, Brett (b) (6) (b) (6) Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; (b) (6) Jeneffer Haynes (b) (6) (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; (b) (6) Isabel Ramsey (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetski]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group



(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy  
 [ (b) (6) Hughes, Eric [ (b) (6) Kurilla, Michael (NIH/NCATS) [E]  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Read, Sarah (NIH/NIAID) [E]  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John  
 [ (b) (6) Paul Gillard [ (b) (6) Hamilton, Holli (OS/ASPR/BARDA)  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=a28fc2f8eb134b00b5eaa4222d0576cc-Holli Hamil]; Modjarrad, Kayvon CIV  
 USARMY MEDCOM WRAIR (USA) [ (b) (6) Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange  
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.com];  
 Schrag, Stephanie (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=9be29b344ba14363bdecaa43582ca226-ZHA6]; Verani, Jennifer R.  
 (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c249692151d46d6ac80cb28ada3d3a0-qzr7]; Thornburg, Natalie  
 (CDC/DDID/NCIRD/DVD) [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d079e00a5649639c6f1425f3bb075f-nax3]; Gonzalez, Nina  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];  
 Wachtel, Jonathan [ (b) (6) Stratton, Benjamin [ (b) (6) Anderson, Margaret  
 [ (b) (6) (b) (6) (b) (6) Bethany Stokes  
 [ (b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=001a98d300d14b20b18c01181eb843e0-Arvinam.Sta]

**Subject:** Canceled: ACTIV Vaccines Working Group meeting  
**Location:** Webex: <https://nih.webex>. (b) (6)

**Start:** 6/9/2020 4:30:00 PM  
**End:** 6/9/2020 5:30:00 PM  
**Show Time As:** Free

**Required Attendees:** (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6) Arvin, Ann; Beth Bell  
 (b) (6) (b) (6) Cavaleri Marco; (b) (6)  
 (b) (6) (b) (6) Greg Glenn; (b) (6) Haynes,  
 Barton; (b) (6) (b) (6) Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E];  
 Messonnier, Nancy (CDC/DDID/NCIRD/OD); Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA); Offit, Paul,  
 (b) (6) Seals, Jonathan (OS/ASPR/BARDA); (b) (6) Tal Zaks  
**Optional Attendees:** Tolman, Brett; (b) (6) Hopps, Markay; Kozlowsk, Mary (NIH/NCI) [C]; Johnson, Maureen  
 (NIH/NCI) [E]; (b) (6) Jeneffer Haynes; (b) (6) (b) (6)  
 (b) (6) Austin, Sarah (NIH/NIAID) [E]; (b) (6) Isabel Ramsey; Parker,  
 Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E];  
 Gadbois, Ellen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T];  
 Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E];  
 Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul  
 Gillard, Hamilton, Holli (OS/ASPR/BARDA), Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA), Kathleen Neuzil;  
 Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Thornburg, Natalie  
 (CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin; Anderson, Margaret;  
 (b) (6) (b) (6) Bethany Stokes; Ann Arvin

To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra | (b) (6) Eisner, Mark | (b) (6) Gottesdiener, Keith | (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurner.m]; Kim, Elizabeth | (b) (6) LaVange, Lisa | (b) (6) Levy, Elliot | (b) (6) Mellors, John W | (b) (6) Menon, Sandeep | (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish | (b) (6) Peppercorn, Amanda | (b) (6) Poole, Mike | (b) (6) Proshan, Michael (NIH/NIAID) [E] | (b) (6) Read, Sarah (NIH/NIAID) [E] | (b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia Coll]; Amanda Peppercorn | (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner | (b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV DTRA RD (USA) | (b) (6) Petrovick, Martha - 0449 - MITLL | (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore];

CC: (b) (6) (b) (6) (b) (6) Garner, Carl  
 | (b) (6)  
 Gonzalez, Nina | (b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange  
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis];  
 Desrosiers, Betsy [elizabeth (b) (6) Jansen, Kathrin | (b) (6) Kurilla, Michael  
 (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI)  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John  
 (b) (6) Biggs, Mary | (b) (6) Butcher, Tina | (b) (6)  
 Demarcus | (b) (6) Macone, Erin | (b) (6) Melencio, Cheryl (FNIH) [T]  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencio]; Salathin, Carla  
 | (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T]  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetski]; James, Stephanie (FNIH)  
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan  
 (b) (6) Tolman, Brett | (b) (6) Alvarez, Rosa | (b) (6) Dana  
 Carluccio | (b) (6) Rose Li Central Account | (b) (6) Margaret  
 Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Lucas Smalldon  
 | (b) (6) Stratton, Benjamin | (b) (6)  
 (b) (6) Mollica, Linda /US | (b) (6) Qashu, Felicia (NIH/OD) [E]  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy  
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B  
 (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary  
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q.  
 | (b) (6) Wung, Peter /US | (b) (6) Hoots, W. Keith (NIH/NHLBI) [E]  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI)  
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI)  
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei  
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave)  
 CIV DTRA J9 (USA) | (b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA)  
 | (b) (6) Elsaid, Olivia | (b) (6) Walker, Paula (NIH/NINDS) [E]  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Bethany Stokes  
 | (b) (6) Sorosa, Alex David | (b) (6) Li, Yuhua-1 [yuhua-  
 1. (b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange  
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]

Start: 11/19/2020 6:00:00 PM  
 End: 11/19/2020 7:00:00 PM

Recurrence: (none)

<b>Required Attendees:</b>	<p>Adarn, Stacey (FNIH) [T]; Garner, Carl; Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark, Gottesdiener, Keith; Hughes, Eric, Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael, Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER), Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Higgs, Elizabeth (NIH/NIAID) [E], Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Re neck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; (b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, E len (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beige, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6) Sizemore, Christine (NIH/FIC) [E]; (b) (6)</p>
<b>Optional Attendees:</b>	<p>(b) (6) Gonzalez, Nina; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin. Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Dana Carluccio; Rose Li Central Account; Margaret Anderson; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Heien Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzeiski, Andre (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Frere, Maria (FNIH) [T]; Elsaid, Olivia; Walker, Paula (NIH/NINDS) [E]; Bethany Stokes; Sorosa, Alex David; Li, Yuhua-1</p>

**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

**Sent:** 4/15/2020 10:09:40 PM

**To:** Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [ (b) (6) Butterson, Joan (b) (6) Collins, Sylva (FDA/CDER) [Sylva.Col (b) (6) Judy Currier (b) (6) De Claro, R. Angelo (FDA/CDER) [ (b) (6) Mark Eisner | (b) (6) Keith Gottesdiener | (b) (6) Eric Hughes | (b) (6) LaVange, Lisa M | (b) (6) Elliott Levy | (b) (6) Sandeep Menon | (b) (6) ; Amanda Peppercorn | (b) (6) Proschan, Michael (NIH/NIAID) [E] | (b) (6) Read, Sarah (NIH/NIAID) [E] | (b) (6) Amanda Peppercorn | (b) (6) Price, Dionne (FDA/CDER) | (b) (6) Rubin, Daniel B. (FDA/CDER) | (b) (6) Shen, Yuan Li (FDA/CDER) | (b) (6) Farley, John (FDA/CDER) (b) (6) Bascles, Lionel | (b) (6) Dickens, Jim (NIH/NCATS) [C] (b) (6) Stein, Peter (FDA/CDER) | (b) (6) Vincent, Michael | (b) (6) ; Desrosiers, Betsy | (b) (6) Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]

**CC:** Mary Biggs | (b) (6) Demarcus | (b) (6) Macone, Erin | (b) (6) Tountas, Karen (FNIH) [T] | (b) (6) Wachtel, Jonathan (b) (6) Elizabeth Kim | (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Rose Li Central Account | (b) (6) Lucas Smalldon | (b) (6) Butcher, Tina | (b) (6) Wholley, David (FNIH) [T] | (b) (6) Melencio, Cheryl (FNIH) [T] | (b) (6) Kelly Beazley | (b) (6) Wung, Peter /US | (b) (6) Greg Richards | (b) (6)

**Subject:** ACTIV TX-C inical WG Master Protocol Subgroup - 2nd Meeting (Materials Attached)

**Attachments:** Therapeutics-Clinical MP Subgroup Meeting Agenda\_04162020.pdf; Therapeutics-Clinical\_MP Subgroup\_16Apr2020 Meeting Guide pdf; ACTG Protocol - A5395 f1-041320.pdf; ACTT Protocol No. 20-0006 - v3.3, 12Apr2020 DRAFT.pdf; REMAP-CAP+-+Pandemic+Appendix+to+Core+-+V1.1+-+20200212\_WM.pd.pdf; REMAP-CAP+Core+Protocol+V3+-+10+July+2019\_WM.pd.pdf

**Location:** <https://zoom.us/> (b) (6)

**Start:** 4/16/2020 3:00:00 PM

**End:** 4/16/2020 4:00:00 PM

**Show Time As:** Busy

**Required Attendees:** Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson, Collins, Sylva (FDA/CDER), Judy Currier; De Claro, R. Angelo (FDA/CDER), Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E], Amanda Peppercorn; Price Dionne (FDA/CDER), Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER), Farley, John (FDA/CDER), Bascles, Lionel; Goff, David (NIH/NHLBI) [E]; Dickens, Jim (NIH/NCATS) [C]; Stein, Peter (FDA/CDER); Vincent, Michael; Desrosiers, Betsy

**Optional Attendees:** Mary Biggs, Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Rose Li Central Account; Lucas Smalldon; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Kelly Beazley; Wung, Peter /US

Dear ACTIV Therapeutics-Clinical WG Master Protocol Subgroup Members,

Thank you all for being so quick to reply and making yourselves available for a second meeting on such short notice!

As discussed yesterday, we have tried to synthesize the main points from our discuss and put together just a few slides to pressure test what we thought we heard.



As we think we defined the patient populations and the order of priority with which we should address them during our last meeting. We hope to come out of today's meeting with a decision on whether to engage/sign on to existing master protocols and enhance them (new agents, more resources, more sites, etc.) or to create a who new protocol.

Please see attached:

1. Agenda
2. Slides for today's meeting
3. Copies of the protocols for today's discuss that we could access
  - a. ACTG
  - b. ACTT v2
  - c. REMAP-CAP + Pandemic Amendment
    - i. <https://www.remapcap.org/coronavirus> provides a summary of changes to the REMAP-CAP protocol in order to update to the COVID population

NOTE: We are still working on access to ORCHID.

Kind regards,  
Stacey, on behalf of the ACTIV TX-Clinical WG

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Find your local number: <https://zoom.us/u> (b) (6)

**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
**Sent:** 11/13/2020 1:31:58 PM  
**To:** Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan\_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra | (b) (6) Eisner, Mark | (b) (6) Gottesdener, Keith [keith. (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth | (b) (6) LaVange, Lisa | (b) (6) Levy, Elliot | (b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep | (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish | (b) (6) Peppercorn, Amanda | (b) (6) Poole, Mike | (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collins]; Amanda Peppercorn | (b) (6) Garner, Carl | (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner | (b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative

Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae0627d74e3cbd894e30160869f0-jbeigel]; Philips, L Revell CIV DTRA RD (USA) | (b) (6) Petrovick, Martha - 0449 - MITLL | (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy | (b) (6) Jansen, Kathrin | (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n], Young, John (b) (6) Biggs, Mary | (b) (6) Butcher, Tina | (b) (6) Demarcus | (b) (6) Macone, Erin | (b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencio]; Salathin, Carla | (b) (6) ]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan (b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio | (b) (6) Rose Li Central Account | (b) (6) ]; Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso], Lucas Smaldon | (b) (6) ]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188]; (b) (6) Mollica, Linda /US | (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Wung, Peter /US | (b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) | (b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) | (b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acb5fd03bcfd32930-walkerpl]; Bethany Stokes | (b) (6) asorosa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]

**Subject:** Post-Acute Sequelae of COVID19 Workshop Dec 3-4

**Attachments:** Post-AcuteCOVIDWorkshopAgenda.pdf

Dear ACTIV TX-Clinical WG Members,

I am reaching out to let you know that NIAID with assistance from NHLBI and other NIH ICs is planning a workshop Dec 3-4 on Post-Acute Sequelae of COVID19 (i.e. Long COVID).

The agenda is attached and the website to register is here: <https://cvent.me/MQAxOa>

Given that this meeting will occur during our normal meeting time, we will be canceling our working group meeting on December 3<sup>rd</sup> to allow all those who wish to attend this conference to do so.

If you have any questions, please do not hesitate to reach out.

Thanks,  
Stacey

**Stacey J. Adam, PhD**  
Director, Cancer  
Research Partnerships  
**Foundation for the National Institutes of Health**  
Direct: (b) (6) Mobile: (b) (6)  
[fnih.org](http://fnih.org)  
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: [fnih.org/pandemic](http://fnih.org/pandemic)



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**From:** George, Jill (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F90BFFB4B3A2464382ADC29B127AED4E-GEORGE.IL]  
**Sent:** 8/28/2020 2:41:34 PM  
**To:** Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]  
**Subject:** RE: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Got it. Will switch on my end to also have it right.

**From:** Parker, Ashley (NIH/OD) [E] < > (b) (6)  
**Sent:** Friday, August 28, 2020 10:27 AM  
**To:** George, Jill (NIH/OD) [E] < > (b) (6)  
**Subject:** RE: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Thanks! The vaccines and CT capacity WG are done but I will move the checks!

**From:** George, Jill (NIH/OD) [E] < > (b) (6)  
**Sent:** Friday, August 28, 2020 9:45 AM  
**To:** Parker, Ashley (NIH/OD) [E] < > (b) (6) >  
**Subject:** RE: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Thanks for converting! Pretty soon you won't need me at all! 😊  
Move the animated the checks as needed. Made a logical assumption, but could be wrong!  
Jill

**From:** Parker, Ashley (NIH/OD) [E] < > (b) (6) >  
**Sent:** Friday, August 28, 2020 9:15 AM  
**To:** George, Jill (NIH/OD) [E] < > (b) (6)  
**Subject:** RE: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

I converted them PP.

**From:** George, Jill (NIH/OD) [E] < > (b) (6)  
**Sent:** Friday, August 28, 2020 9:12 AM  
**To:** Parker, Ashley (NIH/OD) [E] < > (b) (6)  
**Subject:** RE: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Darn. These are all PDFs. Any PPTX files?

**From:** Parker, Ashley (NIH/OD) [E] < > (b) (6)  
**Sent:** Friday, August 28, 2020 8:49 AM  
**To:** George, Jill (NIH/OD) [E] < > (b) (6)  
**Subject:** FW: Materials for August 26 ACTIV Partnership Leadership Team Teleconference  
**Importance:** High

**From:** Melencio, Cheryl (FNIH) [T] < > (b) (6) On Behalf Of Wholley, David (FNIH) [T]  
**Sent:** Tuesday, August 25, 2020 9:47 PM  
**To:** Austin, Christopher (NIH/NCATS) [E] < > (b) (6) Bancel, Stephane



< (b) (6) Carter, Kara (b) (6) Cavaleri, Marco  
 < (b) (6) : Cihlar, Tomas (b) (6) >; Collins, Francis (NIH/OD) [E]  
 (b) (6) >; Corey, Larry (b) (6) Culp, Michelle (NIH/OD) [E] < (b) (6)  
 Disbrow, Gary (OS/ASPR/BARDA) (b) (6) >; Dolsten, Mikael (b) (6) >; Erbeling,  
 Emily (NIH/NIAID) [E] (b) (6) Erck, Stan < (b) (6) Fauci, Anthony (NIH/NIAID) [E]  
 (b) (6) Freire, Maria (FNIH) [T] (b) (6) Gadbois, Ellen (NIH/OD) [E]  
 (b) (6) >; Gibbons, Gary (NIH/NHLBI) [E] < (b) (6) >; Hudson, Thomas  
 (b) (6) ; James, Stephanie (FNIH) [T] (b) (6) >; Johnson, Robert (OS/ASPR/BARDA)  
 (b) (6) Kramer, Lynn (b) (6) >; Lane, Cliff (NIH/NIAID) [E] (b) (6)  
 Lepore, John (b) (6) Marks, Peter (FDA/CBER) < (b) (6) >; Marston, Hilary  
 (NIH/NIAID) [E] (b) (6) Mascola, John (NIH/VRC) [E] (b) (6) ; Meeker, David  
 (b) (6) Menetski, Joseph (FNIH) [T] (b) (6) (Messonnier, Nancy  
 (CDC/DDID/NCIRD/OD) <(b) (6) >; Pandya, Hitesh (b) (6) Pangalos, Mene  
 (b) (6) ; Pao, William < (b) (6) . Parker, Ashley (NIH/OD) [E]  
 < (b) (6) Paul, Steve < (b) (6) Perlmutter, Roger < (b) (6)  
 Plenge, Robert < (b) (6) >; Plump, Andy (b) (6) >; Rachel Ramoni  
 (b) (6) Rasi, Guido (b) (6) >; Reed, John (b) (6) ; Reese, David  
 (b) (6) Rouse, Doris < (b) (6) Santos, Michael (FNIH) [T] < (b) (6) Skovronsky,  
 Daniel < (b) (6) ; Stein, Peter (FDA/CDER) (b) (6) Stoffels, Paul  
 (b) (6) Tabak, Lawrence (NIH/OD) [E] (b) (6) ; Talley, Michael  
 (b) (6) >; Tsai, John (b) (6) Vessey, Rupert < (b) (6) Virgin, Skip  
 (b) (6) >; Wholley, David (FNIH) [T] (b) (6) ; Woodcock, Janet (FDA/CDER)  
 (b) (6) >; Young, John (b) (6) ; Colvis, Christine (NIH/NCATS) [E]  
 < (b) (6) Desrosiers, Betsy (b) (6) ; Eric Hughes  
 (b) (6) Jansen, Kathrin < (b) (6) >; Kurilla, Michael (NIH/NCATS) [E]  
 (b) (6) Lowy, Douglas (NCI) (b) (6) Read, Sarah (NIH/NIAID) [E] (b) (6)  
 Young, John < (b) (6)  
 Cc: Adam, Stacey (FNIH) [T] (b) (6) ; Alvarez, Rosa < (b) (6) Anderson, Margaret  
 (b) (6) Chen, Helen (b) (6) . Elsaid, Olivia < (b) (6)  
 Gonzalez, Nina (b) (6) >; Hawk, Harrison (b) (6) ; Menetski, Joseph (FNIH) [T]  
 (b) (6) ; Santos, Michael (FNIH) [T] < (b) (6) Stratton, Benjamin (b) (6) >;  
 btolman < (b) (6) . Tountas, Karen (FNIH) [T] (b) (6) Wachtel, Jonathan  
 (b) (6) Wholley, David (FNIH) [T] <(b) (6) ; Anderson, James (NIH/OD) [E]  
 (b) (6) Austin, Christopher (NIH/NCATS) [E] (b) (6) ; Burklow, John (NIH/OD) [E]  
 < (b) (6) Castillejos, Carlos < (b) (6) : Culp, Michelle (NIH/OD) [E]  
 < (b) (6) ; FNIH Central Account (b) (6) ; Freire, Maria (FNIH) [T]  
 < (b) (6) Gadbois, Ellen (NIH/OD) [E] < (b) (6) Hallett, Adrienne (NIH/OD) [E]  
 < (b) (6) Lane, Cliff (NIH/NIAID) [E] (b) (6) >; Myles, Renate (NIH/OD) [E]  
 < (b) (6) ; Parker, Ashley (NIH/OD) [E] (b) (6) >; Tabak, Lawrence (NIH/OD) [E]  
 < (b) (6) Wolinetz, Carrie (NIH/OD) [E] (b) (6) Burklow, John (NIH/OD) [E]  
 < (b) (6) Gorman, Greta (FNIH) [T] < (b) (6) Hallett, Adrienne (NIH/OD) [E]  
 < (b) (6) >; Meltzer, Abbey (FNIH) [T] < (b) (6) >; Myles, Renate (NIH/OD) [E]  
 (b) (6) >; Wolinetz, Carrie (NIH/OD) [E] (b) (6) . Lucas Smalldon  
 (b) (6) Villafana, Tonya (b) (6) >; Brian Rosen  
 (b) (6)

**Subject:** Materials for August 26 ACTIV Partnership Leadership Team Teleconference

**Importance:** High

Dear Colleagues.

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from 3:00 – 4:00 PM Eastern U.S. time tomorrow, Wednesday August 26. (As a reminder, this meeting and future LT meetings are 60 minutes

in length.) I have also attached notes from our July 29 Leadership Team meeting as well as our last ACTIV EC meeting on August 14.

The Zoom meeting information is:

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

**David Wholley**  
**Senior Vice-President, Research Partnerships**  
**Foundation for the National Institutes of Health**

(b) (6)

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**Sent:** 12/3/2020 2:58:38 PM  
**To:** Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) m;  
(b) (6) Annaliesa. (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];  
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];  
(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];  
(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [ (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [ (b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [ (b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6)  
**CC:** Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [ (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim, Elizabeth [ (b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan (b) (6) Prabhavathi  
Fernandes [ (b) (6) Diamond, Michael [ (b) (6) Rose Li  
[ (b) (6) Dana Carluccio [ (b) (6) Lagos, Enrique (NIH/NCATS)  
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha  
(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];  
Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D  
[ (b) (6) Dave Frankowski [ (b) (6) antoinette\_baric  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userb6b844cf]; Lowy,  
Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188];  
Gadbois, El en (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James  
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]

**Subject:** RE: ACTIV Preclinical full working group

**Attachments:** 20201203\_Preclinical WG\_Strategic Objective Updates.pptx

Hi all,

Thank you for the great discussion yesterday. Based on your feedback, we have reworked the Preclinical WG Strategic Objectives (attached). This was mostly a consolidation effort - Objectives 2 & 3 are now subcategories under Objective 1.

As Joe mentioned during the WG meeting, we still need your feedback on the 'preparedness' objective (slides 7 & 8). Please take a look at the attached version and **respond with any suggestions or modifications** you have. We truly appreciate all of your help on these objectives to date.

Thank you,  
Harrison

**Harrison Hawk**  
Deloitte Consulting LLP  
Mobile: + (b) (6)  
[www.deloitte.com](http://www.deloitte.com)

-----Original Appointment-----

**From:** Menetski, Joseph (FNIH) [T] < (b) (6) >

**Sent:** Tuesday, August 4, 2020 9:10 AM

**To:** Menetski, Joseph (FNIH) [T]; Hawk, Harrison; Hild, Sheri (NIH/OD) [E]; (b) (6)

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Ottinger, Elizabeth (NIH/NCATS) [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E];



Collins, Francis (NIH/OD) [E]; (b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6)  
**Cc:** Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria, Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael, Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski, Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]

**Subject:** ACTIV Preclinical full working group

**When:** Wednesday, December 2, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

**Where:** <https://fnih.zoom.us/> (b) (6)

-----Original Appointment-----

**From:** Menetski, Joseph (FNIH) [T] (b) (6)

**Sent:** Tuesday, April 14, 2020 6:44 PM

**To:** Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E]; (b) (6) ; (b) (6)  
(b) (6) ; Baric, Ralph; (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; (b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar, Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA), Punturieri, Antonello (NIH/NHLBI) [E], Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6)  
**Cc:** Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski, Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]

**Subject:** ACTIV Preclinical full working group

**When:** Occurs every Wednesday effective 4/22/2020 until 12/23/2020 from 10:00 AM to 11:00 AM Eastern Standard Time.

**Where:** <https://fnih.zoom> (b) (6)

Changing time for preclinical WG

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**From:** John Lepore [ (b) (6) ]  
**Sent:** 4/9/2020 12:38:28 AM  
**To:** Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]  
**CC:** Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]  
**Subject:** RE: URGENT: Invitation to join the Vaccines Working Group of the COVID PPP

Dear Francis -

Thank you very much for sponsoring this critical initiative and for enabling GSK to contribute.

Please do reach out if you see any other way we could be of help.

With best wishes -

John

**John Lepore**  
**SVP, Head of Research**

**GSK**  
1250 S. Collegeville Road, Mail Code UP4-4400, Collegeville, PA 19426, US

**Email** (b) (6)  
**Tel** (b) (6)  
**Mobile** (b) (6)



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**From:** Collins, Francis (NIH/OD) [E] < (b) (6) >  
**Sent:** Wednesday, April 08, 2020 8:27 PM  
**To:** Emmanuel Hanon < (b) (6) >  
**Cc:** Melencio, Cheryl (FNIH) [T] < (b) (6) > Santos, Michael (FNIH) [T] < (b) (6) > Wholley, David (FNIH) [T] < (b) (6) > John Lepore < (b) (6) >  
**Subject:** URGENT: Invitation to join the Vaccines Working Group of the COVID PPP

EXTERNAL

Dear Dr. Hanon,

Addressing the COVID-19 pandemic is an urgent priority for the entire biomedical research community. Appropriately, the response has been broad and immediate, with many individuals and organizations already dedicated to applying their capabilities to respond. But there is still no proven treatment, and safe and effective vaccines are many months away.

APAR0000026842-2517706

NIH has been working at the forefront of addressing the crisis, including rapidly launching its own clinical trials of therapeutics and a vaccine candidate. But given the seriousness of this global public health crisis, it is time to broaden the response and create a focused public-private partnership with FDA, industry, and academic scientists to further accelerate progress against COVID and the threat of future pandemics. This past Friday I led an initial discussion convened by the Foundation for the National Institutes of Health (FNIH) to decide on the initial research agenda for the partnership. There was broad support from all sectors for this model — with some harkening back to a similar partnership that led to the development of antivirals for HIV/AIDS many years ago. Inspired by the shared embrace of a call to action, we are immediately launching efforts to collaborate in four key areas—accelerating preclinical therapeutic development, optimizing clinical therapeutic development, coordinating clinical trials capacity, and supporting effective vaccine development. Those four areas, and a summary of the meeting, are described in the attached document.

Each area will be powered by a nimble Working Group that includes appropriate domain expertise drawn from among our stakeholders. **You have been recommended to us by John Lepore as a member of the Vaccines Working Group.** The primary objective of this working group is to provide a collaborative framework for advancing vaccine development. I expect this will require a significant investment of your time when I know time is scarce. But these very serious circumstances call for full dedication to action from us all. I am personally committed to doing everything possible to support the execution of this partnership, and would be deeply appreciative if you will contribute your talents to this important effort.

Please direct your response to this invitation by Thursday April 9 (tomorrow! sorry this is such short notice) at 12pm EDT to Cheryl Melencio (b) (6). You may send any questions to Mike Santos (b) (6) at FNIH. A calendar invitation to the initial meeting of the Working Group will be sent out shortly after the response deadline.

I look forward to working with you on this critical effort.

Best,  
Francis S. Collins, M.D., Ph.D.  
Director, NIH

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**Sent:** 7/21/2020 7:19:34 PM

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Meeker [	(b) (6)	Dana Carluccio [	(b) (6)	Hawk, Harrison
[	(b) (6)	Lucas Smalldon [	(b) (6)	Hamilton, Nancy
[	(b) (6)	Lowy, Douglas (NIH/NCI) [E]	(b) (6)	]; Vessey, Rupert
[	(b) (6)	]		

**Subject:** ACTIV Leadership Team Call #7

**Location:** <https://fnih.zoom.us/> (b) (6)

**Start:** 8/26/2020 7:00:00 PM

**End:** 8/26/2020 8:00:00 PM

**Show Time As:** Busy

**Required Attendees:** Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Erck, Stan; Fauc, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; G bbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E] Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ash ey (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Ras, Guido; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholey, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy, Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]. Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Villafana, Tonya; Brian Rosen

**Optional Attendees:** Adam, Stacey (FNIH) [T]; Alvarez, Rosa, Anderson, Margaret; Chen, Helen; Elsaid, Ol via; Gonzalez, Nina; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T], Wachtel, Jonathan, Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hardesty, Rebecca (NIH/OD) [E]; Lagos, Enr que (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Gorman, Greta (FNIH) [T]; Meltzer, Abbey (FNIH) [T]; Togashi, Mieko (NIH/NCI) [E]. Underwood, Nancy; Zotto I, Jessica; Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/MAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C], Edl, Susan; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Lever, Susan; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth, Perala, Mie; Protasiewicz, Ann, Riccobene, Kim, R ggjn, Mary; Ripley, Nadege, Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; David Meeker; Dana Carluccio; Hawk, Harrison; Vessey, Rupert, Lucas Smalldon; Hamilton, Nancy; Lowy, Douglas (NIH/NCI) [E]

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**Subject:** Follow up from the ACTIV Therapeutics-Clinical Working Group Meeting

**Attachments:** 2020-12-17\_TX-Clinical\_WG\_Meeting\_Summary.pdf

Dear ACTIV TX-Clinical WG,

Thank you all for a great final meeting of the year!

First, I wanted to share with you all the links to the Post-COVID-19 Sequelae Workshop the Dr. Lerner presented on at the meeting. The links to the various sessions are below.

Day 1:

<https://videocast.nih.gov/watch=38878>

Day 2:

<https://videocast.nih.gov/watch=38879>

**Breakout Sessions'**

<https://videocast.nih.gov/watch=38882> (Neurological/Psychiatric/Neuromuscular)

<https://videocast.nih.gov/watch=38880> (Cardiovascular)

<https://videocast.nih.gov/watch=38884> (Pulmonary)

<https://videocast.nih.gov/watch=38883> (Renal/GI/Metabolic)

<https://videocast.nih.gov/watch=38885> (Immunologic/Rheumatologic)

<https://videocast.nih.gov/watch=38881> (Pediatric)

Second, I am attaching the summary of the meeting. If you have any additions or amendments, please let me know. Finally, if you have any further suggestions on the IDWeek suggested session, please be sure to let us know before the end of the year.

Thanks,

Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

Direct: (b) (6) Mobile: (b) (6)

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**From:** Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA74284158B86087D08B628E6F-MELENCIOC]  
**Sent:** 5/14/2020 2:30:51 PM  
**To:** Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]  
**Subject:** RE: JAMA Viewpoint on ACTIV: please review

Here are the Executive Committee emails:

Collins, Francis (NIH/OD) [E] (b) (6), Fauci, Anthony (NIH/NIAID) [E] (b) (6), Gibbons, Gary (NIH/NHLBI) [E] (b) (6), Paul (b) (6), Pao, William (b) (6), Dolsten, Mikael (b) (6)

**Cheryl Melencio**  
Administrative Manager, Research Partnerships  
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(b) (6)  
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**From:** Parker, Ashley (NIH/OD) [E] <(b) (6)>  
**Sent:** Thursday, May 14, 2020 10:16 AM  
**To:** Collins, Francis (NIH/OD) [E] <(b) (6)> Myles, Renate (NIH/OD) [E] (b) (6) Kolberg, Rebecca (NIH/OD) [E] <(b) (6)>  
**Cc:** Burklow, John (NIH/OD) [E] <(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)>  
Wholley, David (FNIH) [T] <(b) (6)> Melencio, Cheryl (FNIH) [T] <(b) (6)>  
**Subject:** RE: JAMA Viewpoint on ACTIV: please review

Hi Francis,

David forwarded the emails this morning. Please see below to make it easy to send.

I've pasted a slightly revised draft email OCPL provided (to also cc Renate, Abbey and David?). Renate – there are a few new members working group members, we can work together to update the list.

**To:**  
**Cc:** Myles, Renate (NIH/OD) [E] (b) (6) Meltzer, Abbey (FNIH) [T] <(b) (6)> Wholley, David (FNIH) [T] (b) (6)  
**Bcc:** Stoffels, Paul <(b) (6)> (b) (6); Fauci, Anthony (NIH/NIAID) [E] (b) (6); Gibbons, Gary (NIH/NHLBI) [E] (b) (6); Pao, William (b) (6); Woodcock, Janet (FDA/CDER) (b) (6); Arvin, Ann (b) (6); Buchbinder, Susan (b) (6)

< Emilio (b) (6) Corey, Larry < (b) (6) Davis, Mark < (b) (6) Emini,  
 (b) (6) Hanon, Emmanuel < (b) (6) Haynes, Barton  
 (b) (6) ; Hotez, Peter (b) (6) >; Jansen, Kathrin (b) (6)  
 Lanzavecchia, Antonio (b) (6) Lowy, Douglas (NIH/NCI) [E] < (b) (6) Marks, Peter  
 (FDA/CBER) (b) (6) Mascola, John (b) (6) >; Messonnier, Nancy  
 (CDC/DDID/NCIRD/OD) (b) (6) >; Offit, Paul (b) (6) Parker, Ashley (NIH/OD) [E]  
 (b) (6) Santos, Michael (FNIH) [T] (b) (6) Santos, Nancy (b) (6)  
 Schuitemaker, Hanneke (b) (6) >; Tartaglia, Jim (b) (6) ; Tolman, Brett  
 < (b) (6) >; Zaks, Tal (b) (6) ; Qashu, Felicia (NIH/OD) [E] < (b) (6)  
 Michael, Nelson, (b) (6) Adam, Stacey (FNIH) [T] < (b) (6) Bascles, Lionel  
 (b) (6) >; Cohen, Myron (b) (6) Corey, Larry (b) (6)  
 Desrosiers, Betsy (b) (6) >; Dickens, Jim (NIH/NCATS) [C] (b) (6)  
 Doroshow, James (NIH/NCI) [E] (b) (6) Goff, David (NIH/NHLBI) [E] < (b) (6) >; Heaton,  
 Penny < (b) (6) Kurilla, Mike < (b) (6) Nayak, Seema (NIH/NIAID) [E]  
 (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Payton, Manzine  
 (b) (6) >; Resnansky, Laura (b) (6) Srinivasan, Badhri  
 < (b) (6) >; Stein, Peter (FDA/CDER) (b) (6) [T]  
 ≤ (b) (6) Vincent, Mike (b) (6) Wachtel, Jonathan < (b) (6)  
 Woodcock, Janet (FDA/CDER) (b) (6) Sizemore, Christine  
 (NIH/FIC) [E] (b) (6) >; Victoria Davey <v.ctoria (b) (6) Qashu, Felicia (NIH/OD) [E]  
 (b) (6) Weinmann, < (b) (6) Mensah, < (b) (6)  
 Adam, Stacey (FNIH) [T] < (b) (6) ; Bozzette, Sam (NIH/NCATS) [E] < (b) (6) ; Buchman, Tim  
 (OS/ASPR/BARDA) (CTR) < (b) (6) >; Butters, Joan (b) (6) Currier, Judy  
 < (b) (6) De Claro, R. Angelo (FDA/CDER) < (b) (6) Draghia-Akli, Ruxandra  
 < (b) (6) Eisner, Mark (b) (6) ) Garner,  
 Carlos < (b) (6) >Gottesdiener, Keith (b) (6) Hughes, Eric  
 (b) (6) >; Kim, Elizabeth (b) (6) ; LaVange, Lisa (b) (6) >; Levy, Elliot  
 < (b) (6) Mellors, John < (b) (6) Menon, Sandeep < (b) (6) Parker,  
 Ashley (NIH/OD) [E] (b) (6) Patel, Naimish (b) (6) Peppercorn, Amanda  
 (b) (6) >; Poole, Mike (b) (6) ; Prosch, Michael  
 (b) (6) >; Read, Sarah (b) (6) >; Santos, Michael (FNIH) [T] (b) (6) Shen,  
 Yuan Li (FDA/CDER) (b) (6) , Stein, Peter (FDA/CDER) < (b) (6) Higgs, Elizabeth  
 ≤ (b) (6) ; Koroshetz, Walter (b) (6) >; Farley, John (b) (6)  
 (b) (6) Qashu, Felicia < (b) (6) >; Burgess,  
 Timothy < (b) (6) Reineck, Lora < (b) (6) Aggarwal, Neil < (b) (6)

Subject: ACTION: Making your ACTIV Participation Public

Dear Colleagues:

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer and David Wholey by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed as part of the ACTIV membership.**

Thanks,  
Francis

Francis Collins, MD, PhD  
NIH Director

APAR0000002913-2517710



**From:** Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

**Sent:** 5/7/2020 2:11:25 AM

**To:** Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan\_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [E] (b) (6) Eisner, Mark [E] (b) (6) Gottesdiener, Keith (b) (6) Hughes, Eric [E] (b) (6) Judy Currier [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [E] (b) (6) LaVange, Lisa [E] (b) (6) Levy, Elliot [E] (b) (6) Mellors, John W [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [E] (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [naimish.patel@sanofi.com]; Peppercorn, Amanda [E] (b) (6) Poole, Mike [E] (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collins]; Amanda Peppercorn [E] (b) (6) Garner, Carl [E] (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw];

**CC:** Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [E] (b) (6) Jansen, Kathrin [E] (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [E] (b) (6) Biggs, Mary [E] (b) (6) Butcher, Tina [E] (b) (6) Demarcus [E] (b) (6) Macone, Erin [E] (b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [E] (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan [E] (b) (6) Tolman, Brett [E] (b) (6) Alvarez, Rosa [E] (b) (6)

Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [ (b) (6) Rose  
Li Central Account [ (b) (6) Anderson, Margaret [ (b) (6) Lucas  
Smaldon [Luca (b) (6) Stratton, Benjamin [ (b) (6)  
(b) (6) Mollica, Linda /US [ (b) (6) Qashu, Felicia (NIH/OD) [E]  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]

**Subject:** Material for ACTIV TX-Clinical Working Group #5

**Attachments:** ACTIV Therapeutics-Clinical WG 7May2020 Meeting Guide.pdf; ACTIV Therapeut.cs-Clinical WG 7May2020 Agenda.pdf

Dear TX-Clinical Working Group and Invite Guests,

Please find attached the materials for our meeting tomorrow. We will have both the Agent Prioritization and Master Protocol Subgroups discuss ongoing efforts and the co-chairs will provide a quick update from the ACTIV Leadership meeting yesterday.

Please note that the drugs that have been selected for by the Agent Prioritization team are still being held internal to ACTIV while participation is discussed with the companies, so we would ask that you not share these outside the group.

Thanks,  
Stacey

Stacey J. Adam, PhD  
Director, Cancer  
Research Partnerships  
Direct: (b) (6) Mobile: (b) (6)

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US (Germantown)

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US (Germantown)  
US (Chicago)  
US (San Jose)  
US (Tacoma)  
US (Houston)  
US (San Jose)

Meeting ID: (b) (6)  
Password: (b) (6)  
Find your local number: <https://fnih.zoom.us> (b) (6)

**From:** Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]  
**Sent:** 4/15/2020 6:08:29 PM  
**To:** Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]  
**Subject:** RE: List -- just copy and paste in bcc. lists of April 3 plus working groups  
**Attachments:** Master list for ACTIV 041520.xlsx

Francis -- the following emails were missing from the list that went out, please see 8 emails listed below

Cheryl -- attached is a revised master list (114 contacts) with names and emails which includes everyone.

Disbrow, Gary (OS/ASPR/BARDA) < (b) (6)  
Kim, Elizabeth < (b) (6)  
Marston, Hilary (NIH/NIAID) [E] (b) (6)  
Paul, Steve < (b) (6)  
Payne, David < (b) (6)  
Plump, Andy <a (b) (6) >  
Santos, Nancy < (b) (6)  
Shen, Yuan Li (FDA/CDER) <Y (b) (6)

Thanks,  
Ashley

**From:** Collins, Francis (NIH/OD) [E] < (b) (6)  
**Sent:** Wednesday, April 15, 2020 11:39 AM  
**To:** Melencio, Cheryl (FNIH) [T] < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6)  
**Subject:** RE: List -- just copy and paste in bcc. lists of April 3 plus working groups

I already sent the other list, given the time sensitivity. What has been added here that wasn't in the other one?

**From:** Melencio, Cheryl (FNIH) [T] < (b) (6) >  
**Sent:** Wednesday, April 15, 2020 11:19 AM  
**To:** Parker, Ashley (NIH/OD) [E] < (b) (6) Collins, Francis (NIH/OD) [E] < (b) (6)  
**Subject:** List -- just copy and paste in bcc. lists of April 3 plus working groups

Austin, Christopher (NIH/NCATS) [E] < (b) (6) Bright, Rick < (b) (6) Collins, Francis (NIH/OD) [E] < (b) (6) Corey, Larry (b) (6) Disbrow, Gary (OS/ASPR/BARDA) < (b) (6) Dolsten, Mikael (b) (6) >; Erbelding, Emily (NIH/NIAID) [E] < (b) (6) >; Fauci, Anthony (NIH/NIAID) [E] < (b) (6) >; Frankowski, David (b) (6) Hudson, Thomas < (b) (6) >; James, Stephanie (FNIH) [T] < (b) (6) Klock, Kevin (FNIH) [T] < (b) (6) Lane, Cliff (NIH/NIAID) [E] < (b) (6) >; Marks, Peter (FDA/CBER) < (b) (6) Marston, Hilary (NIH/NIAID) [E] < (b) (6) >; Menetski, Joseph (FNIH) [T] < (b) (6) >; Meeker, David (b) (6) Pao, William < (b) (6) >; Pangalos, Mene < (b) (6) >; Perlmutter, Roger < (b) (6) >; Plump, Andy < (b) (6) >; Rasi, Guido < (b) (6) >; Reed, John < (b) (6) >; Rouse,

Doris (b) (6) >; Santos, Michael (FNIH) [T] < (b) (6) Skovronsky, Daniel  
 (b) (6) . Stein, Peter (FDA/CDER) (b) (6) >; Stoffels, Paul  
 (b) (6) ; Tabak, Lawrence (NIH/OD) [E] (b) (6) ov>; Tsai, John  
 (b) >; Vessey, Rupert < (b) (6) ; Virgin, Skip (b) (6) >; Wholley, David  
 (FNIH) [T] < (b) (6) >; Woodcock, Janet (FDA/CDER) (Young, John  
 < (b) (6) Adam, Stacey (FNIH) [T] < (b) (6) >; Bascles, Lionel  
 < (b) (6) Cohen, Myron < (b) (6) Corey, Larry < (b) (6)  
 Desrosiers, Betsy (b) (6) Dickens, Jim (NIH/NCATS) [C] < (b) (6)  
 Doroshov, James (NIH/NCI) [E] (b) (6) >; Goff, David (NIH/NHLBI) [E] < (b) (6) Heaton,  
 Penny < (b) (6) King, James (b) (6) Kurilla, Mike (b) (6) Nayak,  
 Seema (NIH/NIAID) [E] (b) (6) >, Parker, Ashley (NIH/OD) [E] < (b) (6) . Payton, Manzine  
 (b) (6) >; Resnansky, Laura (b) (6) ; Srinivasan, Badhri  
 (b) (6) ; Stein, Peter (FDA/CDER) < (b) (6) : Tountas, Karen (FNIH) [T]  
 (Vincent, Mike (b) (6) >; Wachtel, Jonathan (b) (6)  
 Woodcock, Janet (FDA/CDER) < (b) (6) Adam, Stacey (FNIH) [T] < (b) (6) Bozzette,  
 Sam (NIH/NCATS) [E] (b) (6) >; Buchman, Tim (OS/ASPR/BARDA) (CTR) < (b) (6) ;  
 Butters, Joan < (b) (6) De Claro, R. Angelo (FDA/CDER) (b) (6) >;  
 Draghia-Akli, Ruxandra < (b) (6) . Elsner, Mark < (b) (6) Gottesdiener, Keith  
 (b) (6) : Hughes, Eric (b) (6) >; Judy Currier  
 < (b) (6) Kim, Elizabeth (b) (6) >; LaVange, Lisa (b) (6) >; Levy, Elliot  
 < (b) (6) . Mellors, John < (b) (6) Menon, Sandeep < (b) (6) Parker,  
 Ashley (NIH/OD) [E] (b) (6) Patel, Naimish (b) (6) >; Peppercorn, Amanda  
 < (b) (6) >; Poole, Mike < (b) (6) ; Proschan, Michael  
 < (b) (6) (b) (6) ; Read, Sarah (b) (6) >; Santos, Michael (FNIH) [T] < (b) (6) Shen,  
 Yuan Li (FDA/CDER) (b) (6) (b) (6) Stein, Peter (FDA/CDER) (b) (6) ; Adams, Peter  
 (OS/ASPR/BARDA) < (b) (6) ; Alvarez, Rosa (b) (6) >; Anderson, Annaliesa  
 (b) (6) ; Baric, Ralph (b) (6) Carter, Kara (b) (6)  
 Colvis, Christine < (b) (6) Deming, Damon (FDA/CDER) < (b) (6) Diamond,  
 Michael (b) (6) ; Duncan, Ken (b) (6) >; Fernandes, Prabhavathi  
 (b) (6) >; Gatto, Greg (b) (6) Grobler, Jay < (b) (6) Hewitt, Judith  
 (b) (6) >; Jonson, Samantha (NIH/NCATS) [E] < (b) (6) Lutz, Cat < (b) (6)  
 Menetski, Joseph (FNIH) [T] < (b) (6) Nestle, Frank < (b) (6) >; Ottinger, Liz  
 < (b) (6) >; Parker, Ashley (NIH/OD) [E] (b) (6) Payne, David  
 < (b) (6) Rappaport, Jay (b) (6) , Frank < (b) (6)  
 Young, John < (b) (6) . Annunziato, Paula (b) (6) (b) (6) . Arvin, Ann  
 (b) (6) Buchbinder, Susan (b) (6) >; Corey, Larry < (b) (6) ;  
 Davis, Mark < (b) (6) Ermini, Emilio < (b) (6) Hanon, Emmanuel  
 < (b) (6) Haynes, Barton < (b) (6) . Hotez, Peter < (b) (6) . Jansen,  
 Kathryn (b) (6) >; Lanzavecchia, Antonio < (b) (6) >; Lowy, Douglas (NIH/NCI) [E]  
 < (b) (6) Marks, Peter (FDA/CDER) (b) (6) >; Mascola, John (NIH/VRC) [E]  
 < (b) (6) gov>; Messonnier, Nancy (CDC/DDID/NCIRD/OD) (b) (6) >; Offit, Paul  
 (b) (6) Parker, Ashley (NIH/OD) [E] (b) (6) Santos, Nancy (b) (6) ;  
 Schuitemaker, Hanneke < (b) (6) Tartaglia, Jim < (b) (6) Tolman, Brett  
 (b) (6) (b) (6) (b) (6)

# **Cheryl Melencio**

Administrative Manager, Research Partnerships  
 Foundation for the National Institutes of Health  
 (b) (6)

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**From:** Wooldridge, Shannon (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=385B0C281F104789873E956DC91B7C06-BURDENSE]  
**Sent:** 5/18/2020 1:16:34 PM  
**To:** Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Pollock, Rachel (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4887cb3513e242dfa7d2df712dcc6d6a-pollockrc]  
**Subject:** RE: Time sensitive: Making your ACTIV Participation Public

No replies from Baric, Deming, or Jansen in FC's inbox. I just ran a search.

**From:** Myles, Renate (NIH/OD) [E] < (b) (6) >  
**Sent:** Monday, May 18, 2020 9:16 AM  
**To:** Parker, Ashley (NIH/OD) [E] < (b) (6) > Pollock, Rachel (NIH/OD) [E] < (b) (6) >  
Wooldridge, Shannon (NIH/OD) [E] < (b) (6) >  
**Subject:** RE: Time sensitive: Making your ACTIV Participation Public  
**Importance:** High

Hi Rachel and Shannon:

Would you check FC's mailbox for this information ASAP? We need to launch the webpage this morning.

Thanks,  
Renate

**From:** Parker, Ashley (NIH/OD) [E] < (b) (6) >  
**Sent:** Monday, May 18, 2020 7:57 AM  
**To:** Myles, Renate (NIH/OD) [E] < (b) (6) > Pollock, Rachel (NIH/OD) [E] < (b) (6) > ) (6) >  
Wooldridge, Shannon (NIH/OD) [E] < (b) (6) >  
**Subject:** Re: Time sensitive: Making your ACTIV Participation Public

Hi Renate, Rachel, and Shannon,

We've made lots of progress! Shannon — can we see if the 3 ACTIV participants responded to Dr. Collins privately over the weekend?

Thank you,  
Ashley

On May 17, 2020, at 11:15 PM, Myles, Renate (NIH/OD) [E] < (b) (6) > wrote:

Hi Ashley and Rachel:

Below are the three people I did not hear from. I searched my inbox. Just wanted to double check that they didn't just respond to Francis. Thanks, Renate

Ralph Baric, Ph.D.



William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology  
Professor, Department of Microbiology and Immunology  
University of North Carolina, Gillings School of Global Public Health  
(b) (6)

**Damon Deming, Ph.D.**

Virologist, Division of Antiviral Products, Office of New Drugs  
U.S. Food and Drug Administration  
(b) (6)

**Kathrin Jansen, Ph.D.**

Senior Vice President and Head of Vaccine Research and Development  
Pfizer  
(b) (6)

**From:** Collins, Francis (NIH/OD) [E] <(b) (6)>  
**Sent:** Thursday, May 14, 2020 11:00 AM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Myles, Renate (NIH/OD) [E] (b) (6) >; Meltzer, Abbey (FNIH) [T] (b) (6)  
Wholley, David (FNIH) [T] (b) (6)  
**Subject:** Time sensitive: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.**

Thanks,  
Francis

Francis S. Collins, MD, PhD  
NIH Director

**From:** Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
**Sent:** 4/17/2020 7:48:23 PM  
**To:** Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [ (b) (6) Keith Gottesdiener [ (b) (6) Eric Hughes [ (b) (6) LaVange, Lisa M [ (b) (6) Elliott Levy [ (b) (6) Sandeep Menon [ (b) (6) Amanda Peppercorn [ (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [ (b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]  
**CC:** Mary Biggs [ (b) (6) Demarcus [ (b) (6) Macone, Erin [ (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [ (b) (6) Elizabeth Kim [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Rose Li Central Account [ (b) (6) Lucas Smalldon [ (b) (6) Butcher, Tina [ (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wung, Peter /US [ (b) (6)  
**Subject:** ACTIV Therapeutics-Clinical Master Protocol Subgroup - Meeting #3  
**Location:** <https://fnih.zoom.us/> (b) (6)  
**Start:** 4/20/2020 6:00:00 PM  
**End:** 4/20/2020 7:00:00 PM  
**Show Time As:** Tentative

**Required Attendees:** Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylvia (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes, Lisa LaVange, Elliott Levy; Sandeep Menon; Amanda Peppercorn, Proschan, Michael (NIH/NIAID) [E], Read, Sarah (NIH/NIAID) [E], Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER), Farley, John (FDA/CDER)  
**Optional Attendees:** Mary Biggs, Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Rose Li Central Account; Lucas Smalldon; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Wung, Peter /US

Dear TX-Clinical Master Protocol Subgroup,

This will be our 4<sup>h</sup> meeting. We will update with materials closer to the meeting.

Thanks,

Stacey

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US (Houston)

US (San Jose)

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://fnih.zoom.us/> (b) (6)

**From:** Brodd, Lauren (N H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BA665DEA08E54171B3D6890C2518DDB9-LEPONELM]  
**Sent:** 7/3/2020 7:44:07 PM  
**To:** Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]  
**Subject:** RE: Notes from Wednesday's ACTIV Leadership Team Meeting

Thanks! Happy 4<sup>th</sup> ☺

**From:** Parker, Ashley (NIH/OD) [E] < > (b) (6)  
**Sent:** Friday, July 3, 2020 12:22 PM  
**To:** Brodd, Lauren (NIH/OD) [E] < > (b) (6)  
**Subject:** Fwd: Notes from Wednesday's ACTIV Leadership Team Meeting

FYI

**From:** "Wholley, David (FNIH) [T]" < > (b) (6)  
**Date:** July 3, 2020 at 11:56:07 AM EDT  
**To:** "Austin, Christopher (NIH/NCATS) [E]" < > (b) (6) "Carter, Kara"  
(b) (6) "Cavaleri, Marco" (b) (6) >, "Cihlar, Tomas"  
, "Collins, Francis (NIH/OD) [E]" (b) (6) >, "Corey, Larry"  
(b) (6) "Culp, Michelle (NIH/OD) [E]" (b) (6) >, "Disbrow, Gary"  
{OS/ASPR/BARDA}" (b) (6) "Dolsten, Mikael" (b) (6)  
"Erbelding, Emily (NIH/NIAID) [E]" < > (b) (6) "Fauci, Anthony (NIH/NIAID) [E]"  
(b) (6) , "Freire, Maria (FNIH) [T]" (b) (6) , "Gadbois, Ellen (NIH/OD) [E]"  
> (b) (6) "Gibbons, Gary (NIH/NHLBI) [E]" (b) (6) >, "Hudson, Thomas"  
(b) (6) >, "James, Stephanie (FNIH) [T]" (b) (6) . "Johnson, Robert"  
{OS/ASPR/BARDA}" (b) (6) , "Kramer, Lynn" (b) (6) . "Lane, Cliff"  
{NIH/NIAID} [E]" (b) (6) >, "Lepore, John" (b) (6) . "Marks, Peter"  
{FDA/CBER}" < > (b) (6) . "Marston, Hilary (NIH/NIAID) [E]" < > (b) (6)  
"Mascola, John (NIH/VRC) [E]" (b) (6) Meeker, David" < > (b) (6) >,  
"Menetski, Joseph (FNIH) [T]" < > (b) (6) "Messonnier, Nancy (CDC/DDID/NCIRD/OD)"  
(b) (6) >, "Pandya, Hitesh" (b) (6) . "Pangalos, Mene"  
< > (b) (6) >, "Pao, William" < > (b) (6) "Parker, Ashley"  
{NIH/OD} [E]" (b) (6) > . "Paul, Steve" (b) (6) "Perlmutter, Roger"  
(b) (6) >, "Plenge, Robert" < > (b) (6) . "Plump, Andy"  
Rachel Ramoni (b) (6) "Rasi, Guido"  
'Reed, John" (b) (6) "Reese, David"  
< > (b) (6) . "Rouse, Doris" (b) (6) Santos, Michael (FNIH) [T]"  
(b) (6) . "Skovronsky, Daniel" < > (b) (6) >, "Stein, Peter (FDA/CDER)"  
(b) (6) . "Stoffels, Paul" (b) (6) . "Tabak, Lawrence (NIH/OD) [E]"  
 . "Talley, Michael" (b) (6) "Tsai, John"  
< > (b) (6) . "Vessey, Rupert" (b) (6) . "Virgin, Skip" (b) (6)  
"Woodcock, Janet (FDA/CDER)" < > (b) (6) . "Young, John"  
< > (b) (6) >, "Colvis, Christine (NIH/NCATS) [E]" < > (b) (6)  
"Desrosiers, Betsy" (b) (6) , "Hughes, Eric" (b) (6)  
"Jansen, Kathrin" < > (b) (6) >, "Kurilla, Michael (NIH/NCATS) [E]"  
(b) (6) "Lowy, Douglas (NCI)" (b) (6) , "Read, Sarah (NIH/NIAID) [E]"

(b) (6) >, "Young, John" (b) (6) , "Mallory, Raburn"

(b) (6)

Cc: "Adam, Stacey (FNIH) [T]" (b) (6) "Alvarez, Rosa" < (b) (6)

"Anderson, Margaret" (b) (6) >, "Chen, Helen" (b) (6)

oelsaid (b) (6) , "Gonzalez, Nina" (b) (6) >, "James, Stephanie

{FNIH} [T]" < (b) (6) . "Menetski, Joseph (FNIH) [T]" (b) (6) "Santos, Michael

{FNIH} [T]" < (b) (6) "Stratton, Ben" (b) (6) , "Tolman, Brett"

(b) (6) , "Tountas, Karen (FNIH) [T]" (b) (6) , "Wachtel, Jonathan"

<j (b) (6) , "Anderson, James (NIH/OD) [E]" (b) (6) >, "Austin,

Christopher (NIH/NCATS) [E]" (b) (6) . "Burklow, John (NIH/OD) [E]"

(b) (6) , "Castillejos, Carlos" (b) (6) . "Hallett, Adrienne (NIH/OD) [E]"

(b) (6) . "Lane, Cliff (NIH/NIAID) [E]" (b) (6) >, "Myles, Renate

(NIH/OD) [E]" <(b) (6) , "Wolinetz, Carrie (NIH/OD) [E]" < (b) (6) >

**Subject: Notes from Wednesday's ACTIV Leadership Team Meeting**

Dear All:

Please see the notes from our teleconference on Wednesday, July 1. The action items are listed at the top of the document and so are not being sent out separately.

Please let me know any additional comments or questions regarding these notes.

Thank you again for all your support of and contributions to ACTIV. Have a happy Fourth of July weekend!

David Wholley

**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

**Sent:** 5/16/2020 9:58:35 PM

**To:** Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia Colli]; Judy Carrier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [ (b) (6) Keith Gottesdiener [ (b) (6) Eric Hughes [ (b) (6) LaVange, Lisa M [ (b) (6) Elliott Levy [ (b) (6) Sandeep Menon [ (b) (6) Amanda Peppercorn [ (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [ (b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [ (b) (6) Wung, Peter /US [ (b) (6) Karen Lynn Price [ (b) (6) Pamela Tenaerts, M.D. [ (b) (6) Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Burgess, Timothy [ (b) (6) Beumont-Mauviel, Maria [JRDUS] [ (b) (6) Peeters, Monika [JRDBE] [ (b) (6) Woodfall, Brian [JRDUS] [ (b) (6) Van Heeswijk, Rolf [JRDBE] [ (b) (6) Mary Biggs [ (b) (6) Demarcus [ (b) (6) Macone, Erin [ (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [ (b) (6) Elizabeth Kim [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina [ (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

**Subject:** Follow-up to ACTIV TX-Clinical Master Protocol Subgroup Meeting #17

**Attachments:** ACTIV\_Therapeutics-Clinical\_MP Sub-Group Meeting 15May2020\_Key Takeaways.pdf

Dear ACTIV TX-Clinical Master Protocol Subgroup,

Please find attached the action items and summary notes for yesterday's meeting. Please let us know if you have any additions or amendments.



Thanks,  
Stacey

**Stacey J. Adam, PhD**

Director, Cancer

Research Partnerships

**Foundation for the National Institutes of Health**

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Donate to the FNIH's Pandemic Response Fund to combat COVID-19: [fnih.org/pandemic](http://fnih.org/pandemic)



**From:** Karen Lynn Price [ (b) (6) ]  
**Sent:** 5/22/2020 4:07:06 AM  
**To:** Michael Hughes [ (b) (6) ]; LaVange, Lisa M [ (b) (6) ]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Eron, Joseph J Jr (b) (6); Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Judy Curner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [ (b) (6) ]; Sandeep Menon [ (b) (6) ]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; smith.davey [ (b) (6) ]; chew.kara [ (b) (6) ]; Wohl, David A [ (b) (6) ]; Fischer, William A. II [ (b) (6) ]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; (b) (6); Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; li.jonathan (b) (6); Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eedb7-Gilbert.Mar]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]  
**CC:** DeMarcus, Forrest [ (b) (6) ]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [ (b) (6) ]; Elizabeth Kim [ (b) (6) ]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; roa.jhoanna (b) (6); Smith, David [ (b) (6) ]; Paul Klekotka [ (b) (6) ]; Ajay Nirula [ (b) (6) ]; Elsaid, Olivia [ (b) (6) ]; Robert Jan Benschoep [ (b) (6) ]; Lei Shen [ (b) (6) ]  
**Subject:** Re: [EXTERNAL] Re: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Thanks Lisa and Michael.

Working now to put together more details on the modeling and developing a simulation plan. We look forward to discussing in our stats meetings soon. Whether we end up with Bayesian or frequentist approach, simulation of this design will be required in order to better understand the operating characteristics.

(b) (4)

Thanks,  
Karen

---

**From:** Michael Hughes <(b) (6)>  
**Date:** Thursday, May 21, 2020 at 12:54 PM  
**To:** "LaVange, Lisa M" <(b) (6)> "Proschan, Michael (NIH/NIAID) [E]" <(b) (6)> "Adam, Stacey (FNIH) [T]" <(b) (6)> "Eron, Joseph J Jr" <(b) (6)> "currier.judith" <(b) (6)> Eric Hughes <(b) (6)> Sandeep Menon <(b) (6)> "read.sarah" <(b) (6)> "Price, Dionne (FDA/CDER)" <(b) (6)> "Rubin, Daniel B. (FDA/CDER)" <(b) (6)> "Farley, John (FDA/CDER)" <(b) (6)> Karen Price <(b) (6)> "smith.davey" <(b) (6)> "Wohl, David A" <(b) (6)> "Fischer, William A. II" <(b) (6)> "javan.arzhang" <(b) (6)> "Roa, Jhoanna" <(b) (6)> "kim.peter" <(b) (6)> "li.jonathan" <(b) (6)> "Marks, Gilbert (OS/ASPR/BARDA) (CTR)" <(b) (6)> "Kozak, Marina (OS/ASPR/BARDA)" <(b) (6)> "Tountas, Karen (FNIH) [T]" <(b) (6)> "Wachtel, Jonathan" <(b) (6)> Elizabeth Kim <(b) (6)> "Parker, Ashley (NIH/OD) [E]" <(b) (6)> "roa.jhoanna" <(b) (6)> "Smith, David" <(b) (6)> Paul Klekotka <(b) (6)> Ajay Nirula <(b) (6)> "Elsa d, Olivia" <(b) (6)> Robert Jan Benschop <(b) (6)> Lei Shen <(b) (6)>  
**Subject:** [EXTERNAL] Re: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

**EXTERNAL EMAIL:** Use caution before replying, clicking links, and opening attachments.

Hi Lisa,

That's fine. Perhaps you and Karen could circulate some brief details of the Bayesian model framework and associated priors for each outcome measure you are envisaging? --- I think that would help in moving things along.

Looking forward to discussing,

Michaël

**From:** LaVange, Lisa M <(b) (6)>  
**Sent:** Thursday, May 21, 2020 1:34 PM  
**To:** Michael Hughes; Proschan, Michael (NIH/NIAID) [E]; Eron, Joseph J Jr, Adam, Stacey (FNIH) [T]; currier.judith, Eric Hughes; Sandeep Menon; read.sarah; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; smith.davey; (b) (6) chew.kara; Wohl, David A; Fischer, William A. II; javan.arzhang; Roa, Jhoanna; (b) (6) kim.peter; li.jonathan; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Kozak, Marina (OS/ASPR/BARDA)  
**Cc:** DeMarcus, Forrest; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; roa.jhoanna; Smith, David; Paul Klekotka; Ajay Nirula; Elsaid, Olivia; Robert Jan Benschop; Lei Shen  
**Subject:** RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Thanks, Michael. I believe it is premature to submit the protocol to your internal review committee. My take-away from yesterday's meeting was that the next step would be for the subgroup of statisticians to meet to discuss the simulations required for the revised trial design. The proposed revisions to the design are needed, in my opinion, to give us the type of flexible, fast-moving master protocol we need to screen a large amount of monoclonal antibodies. But we need to work out some of the design details, so let's have that next meeting as planned. Hoping we can schedule it for some time tomorrow and will work with Stacey to find a time.

Lisa

**From:** Michael Hughes [mailto:(b) (6)]  
**Sent:** Thursday, May 21, 2020 11:03 AM  
**To:** Proschan, Michael (NIH/NIAID) [E] <(b) (6)> LaVange, Lisa M  
<(b) (6)> Eron, Joseph J Jr <joseph\_ (b) (6)> Adam, Stacey (FNIH) [T]  
<(b) (6)> currier.judith <(b) (6)> Eric Hughes <(b) (6)>  
Sandeep Menon <(b) (6)> read.sarah <(b) (6)> Price, Dionne  
(FDA/CDER) <(b) (6)> Rubin, Daniel B. (FDA/CDER) <(b) (6)>  
Farley, John (FDA/CDER) <(b) (6)> Karen Lynn Price <price karen (b) (6)>  
smith.davey <(b) (6)> chew.kara <(b) (6)> Wohl,  
David A <david (b) (6)> Fischer, William A. II <william (b) (6)> javan.arzhang  
<(b) (6)> Roa, Jhoanna <(b) (6)> kim.peter  
<(b) (6)> li.jonathan <(b) (6)> Marks, Gilbert (OS/ASPR/BARDA) (CTR)  
<(b) (6)> Kozak, Marina (OS/ASPR/BARDA) <(b) (6)>  
**Cc:** DeMarcus, Forrest <(b) (6)> Tountas, Karen (FNIH) [T] <(b) (6)>  
Wachtel, Jonathan <(b) (6)> Elizabeth Kim <(b) (6)> Parker, Ashley (NIH/OD)  
[E] <(b) (6)> roa.jhoanna <(b) (6)> Smith, David  
<(b) (6)> Paul Klekotka <(b) (6)> Ajay Nirula  
<nirula (b) (6)> Elsaid, Olivia <(b) (6)> Robert Jan Benschop  
<(b) (6)> Lei Shen <(b) (6)>  
**Subject:** Re: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

H1 A.1:

(b) (4)



I would welcome feedback.

Many thanks,

Michael

**From:** Proschan, Michael (NIH/NIAID) [E] <(b) (6)>  
**Sent:** Thursday, May 21, 2020 8:52 AM  
**To:** LaVange, Lisa M; Eron, Joseph J Jr; Adam, Stacey (FNIH) [T]; currier.judith; Eric Hughes; Sandeep Menon; read.sarah; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; smith.davey; Michael Hughes; <(b) (6)>; chew.kara; Wohl, David A; Fischer, William A. II; javan.arzhang; Roa, Jhoanna: <(b) (6)>; kim.peter; li.jonathan; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Kozak, Marina (OS/ASPR/BARDA)  
**Cc:** DeMarcus, Forrest; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; roa.jhoanna; Smith, David; Paul Klekotka; Ajay Nirula; Elsaid, Olivia; Robert Jan Benschop; Lei Shen  
**Subject:** RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

I think the question is whether we could stop early for efficacy as well as stopping early for futility. That could certainly be incorporated if you think there is a realistic possibility of crossing an efficacy boundary after only 50 people. At the halfway point, the O'Brien-Fleming-like spending function boundary for the z-score is close to 3, so you would have to see a very large z-score to stop that early for efficacy.

Mike.

**From:** LaVange, Lisa M <(b) (6)>  
**Sent:** Thursday, May 21, 2020 7:53 AM  
**To:** Eron, Joseph J Jr <(b) (6)>; Adam, Stacey (FNIH) [T] <(b) (6)>; Judy Currier <(b) (6)>; >; Eric Hughes <(b) (6)>; >; Sandeep Menon <(b) (6)>; Proschan, Michael (NIH/NIAID) [E] <(b) (6)>; Read, Sarah (NIH/NIAID) [E] <(b) (6)>; Price, Dionne (FDA/CDER) <(b) (6)>; Rubin, Daniel B. (FDA/CDER) <(b) (6)>; Farley, John (FDA/CDER) <(b) (6)>; Karen Lynn Price <(b) (6)>; <(b) (6)>; Wohl, David A <(b) (6)>; Fischer, William A. II <(b) (6)>; Javan, Arzhang <(b) (6)>; <(b) (6)>; >; Roa, Jhoanna <(b) (6)>; <(b) (6)>; Kim, Peter <(b) (6)>; <(b) (6)>; Jonathan Li <(b) (6)>; Marks, Gilbert <(b) (6)>; <(b) (6)>; Kozak, Marina (OS/ASPR/BARDA) <(b) (6)>; <(b) (6)>  
**Cc:** DeMarcus, Forrest <(b) (6)>; >; Tountas, Karen (FNIH) [T] <(b) (6)>; Wachtel, Jonathan <(b) (6)>; Elizabeth Kim <(b) (6)>; Parker, Ashley (NIH/OD) [E] <(b) (6)>; Jhoanna Roa <(b) (6)>; Smith, David <(b) (6)>; <(b) (6)>; Paul Klekotka <(b) (6)>; Ajay Nirula <(b) (6)>; <(b) (6)>; Elsaid, Olivia <(b) (6)>; >; Robert Jan Benschop <(b) (6)>



(b) (6)

Lei Shen

(b) (6)

**Subject:** RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

This seems reasonable to me. We can define any basis that we think will be important for dropping dose arms or entire agents, having little to go on at this point in terms of what best predicts hospitalizations.

Lisa

**From:** Eron, Joseph J Jr

**Sent:** Wednesday, May 20, 2020 6:23 PM

**To:** Adam, Stacey (FNIH) [T] <(b) (6)>; Judy Currier <(b) (6)>; Eric Hughes  
<(b) (6)>; LaVange, Lisa M <(b) (6)>; Sandeep Menon  
<(b) (6)>; Proschan, Michael (NIH/NIAID) [E] <(b) (6)>; Read,  
Sarah (NIH/NIAID) [E] <(b) (6)>; Price, Dionne (FDA/CDER) <(b) (6)>;  
Rubin, Daniel B. (FDA/CDER) <(b) (6)>; Farley, John (FDA/CDER)  
<(b) (6)>; Karen Lynn Price <(b) (6)>;  
<(b) (6)>; Wohl, David A  
<(b) (6)>; Fischer, William A. II <(b) (6)>; Javan, Arzhang  
(NIH/NIAID) [E] <(b) (6)>; Roa, Jhoanna <(b) (6)>; Kim, Peter  
(NIH/NIAID) [E] <(b) (6)>; Jonathan Li <(b) (6)>; Marks, Gilbert  
(OS/ASPR/BARDA) (CTR) <(b) (6)>; Kozak, Marina (OS/ASPR/BARDA)  
<(b) (6)>  
**Cc:** DeMarcus, Forrest <(b) (6)>; Tountas, Karen (FNIH) [T] <(b) (6)>;  
Wachtel, Jonathan <(b) (6)>; Elizabeth Kim <(b) (6)>; Parker, Ashley (NIH/OD)  
[E] <(b) (6)>; Jhoanna Roa <(b) (6)>; Smith, David  
<(b) (6)>; Paul Klekotka <(b) (6)>; Ajay Nirula  
<(b) (6)>; Elsaid, Olivia <(b) (6)>; Robert Jan Benschop  
<(b) (6)>; Lei Shen <(b) (6)>

**Subject:** RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Here is my question for the group – especially Michael, John and Lisa

My question is whether there could be an interim “activity” analysis similar to the futility analysis listed below – the reason I ask is we have very little longitudinal data on the quantitative viral shedding and it is possible that this endpoint would have substantial power such that 50 patients per arm could provide an antiviral answer.

- If the Phase 2 portion of the Clinical mAb protocol is used for dose finding, this may be challenging with respect to size of the trial (number of treatment arms needed and available sample size per treatment arm). In addition, it may be appropriate to establish an interim futility analysis based on change in quantitative viral shedding to allow for discontinuation of a dose after e.g. 50 rather than 110 patients, or to allow early discontinuation of high doses due to safety findings.

Joe Eron MD

Professor of Medicine

University of North Carolina at Chapel Hill

School of Medicine

(b) (6)

**From:** Adam, Stacey (FNIH) [T] < (b) (6) >

**Sent:** Wednesday, May 20, 2020 5:42 PM

**To:** Judy Currier (b) (6) >; Eric Hughes < (b) (6) >; LaVange, Lisa M  
< (b) (6) >; Sandeep Menon < (b) (6) >; Proschan, Michael (NIH/NIAID)  
[E] (b) (6) >; Read, Sarah (NIH/NIAID) [E] < (b) (6) >; Price, Dionne  
(FDA/CDER) (b) (6) >; Rubin, Daniel B. (FDA/CDER) (b) (6) >;  
Farley, John (FDA/CDER) (b) (6) >; Karen Lynn Price (b) (6) >;  
(b) (6) >; (b) (6) >; (b) (6) >;  
Wohl, David A (b) (6) >; Fischer, William A. II (b) (6) >; Eron,  
Joseph J Jr (b) (6) >; Javan, Arzhang (NIH/NIAID) [E] (b) (6) >; Roa,  
Jhoanna < (b) (6) >; Kim, Peter (NIH/NIAID) [E] < (b) (6) >; Jonathan  
Li (b) (6) >; Marks, Gilbert (OS/ASPR/BARDA) (CTR) < (b) (6) >; Kozak,  
Marina (OS/ASPR/BARDA) < (b) (6) >;  
**Cc:** DeMarcus, Forrest (b) (6) >; Tountas, Karen (FNIH) [T] (b) (6) >;  
Wachtel, Jonathan < (b) (6) >; Elizabeth Kim (b) (6) >; Parker, Ashley (NIH/OD)  
[E] < (b) (6) >; Jhoanna Roa < (b) (6) >; Eron, Joseph J Jr  
(b) (6) >; Smith, David < (b) (6) >; Paul Klekotka  
(b) (6) >; Ajay Nirula <nirula (b) (6) >; Elsaid, Olivia (b) (6) >;  
Robert Jan Benschop (b) (6) >; Lei Shen (b) (6) >;  
**Subject:** RE: Confirmed: ACTIV TX-Clinical mAb Outpatient WT Meeting-3

Dear mAb Outpatient WT,

The FDA team that has been working with ACTIV and sitting in on our writing team meetings for this protocol would like to offer the attached thoughts for the group's consideration on tonight's call.

Also, attaching again the updated synopsis that was discussed with the mAb Steering Committee earlier today.

Thanks.

APAR0000005293-2517720

Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: (b) (6) | Mobile: (b) (6)

Join Zoom Meeting

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US (Houston)  
US (San Jose)  
US (San Jose)

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://fnih.zoom.us/u> (b) (6)

**From:** Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]  
**Sent:** 8/18/2020 3:11:23 PM  
**To:** Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Austin, Christopher (NIH/NCATS) [E] (b) (6) ; Bancel, Stephane [ (b) (6) Carter, Kara [ (b) (6) Cavaleri, Marco [ (b) (6) Cihlar, Tomas [ (b) (6) ; Collins, Francis (NIH/OD) [E] [ (b) (6) ]; Corey, Larry [ (b) (6) Culp, Michelle (NIH/OD) [E] [ (b) (6) Disbrow, Gary (OS/ASPR/BARDA) [ (b) (6) Dolsten, Mikael [ (b) (6) Erbeling, Emily (NIH/NIAID) [E] [ (b) (6) Erck, Stan [ (b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gibbons, Gary (NIH/NHLBI) [E] [ (b) (6) Hudson, Thomas [ (b) (6) James, Stephanie (FNIH) [T] [ (b) (6) Johnson, Robert (OS/ASPR/BARDA) [ (b) (6) Kramer, Lynn [ (b) (6) Lane, Cliff (NIH/NIAID) [E] [ (b) (6) Marks, Peter (FDA/CBER) [ (b) (6) Marston, Hilary (NIH/NIAID) [E] [ (b) (6) Mascola, John (NIH/VRC) [E] [ (b) (6) Meeker, David [ (b) (6) Menetski, Joseph (FNIH) [T] [ (b) (6) Messonnier, Nancy (CDC/DDID/NCIRD/OD) [ (b) (6) Pandya, Hitesh [ (b) (6) Pao, William [will (b) (6) Parker, Ashley (NIH/OD) [E] [ (b) (6) Perlmutter, Roger [ (b) (6) Plenge, Robert [ (b) (6) Plump, Andy [ (b) (6) Rachel Ramoni [ (b) (6) Reed, John [ (b) (6) ; Rouse, Doris [ (b) (6) Santos, Michael (FNIH) [T] [ (b) (6) Skovronsky, Daniel [ (b) (6) Stein, Peter (FDA/CDER) [ (b) (6) ; Stoffels, Paul [ (b) (6) Tabak, Lawrence (NIH/OD) [E] [ (b) (6) ]; Talley, Michael [ (b) (6) Tsai, John [ (b) (6) Vessey, Rupert [ (b) (6) ]; Virgin, Skip [ (b) (6) Wholley, David (FNIH) [T] [ (b) (6) Woodcock, Janet (FDA/CDER) [ (b) (6) Young, John [ (b) (6) Colvis, Christine (NIH/NCATS) [E] [ (b) (6) Desrosiers, Betsy [ (b) (6) Eric Hughes [ (b) (6) Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [ (b) (6) Lowy, Douglas (NCI) [ (b) (6) Read, Sarah (NIH/NIAID) [E] [ (b) (6) Adam, Stacey (FNIH) [T] [ (b) (6) Alvarez, Rosa Maria [ (b) (6) ]; Margaret Anderson [ (b) (6) Chen, Helen Q. [ (b) (6) Elsaid, Olivia [ (b) (6) Gonzalez, Nina [ (b) (6) Hawk, Harrison [ (b) (6) Stratton, Benjamin [ (b) (6) btolman [ (b) (6) Tountas, Karen (FNIH) [T] [ (b) (6) Wachtel, Jonathan [ (b) (6) Anderson, James (NIH/OD) [E] [ (b) (6) Castillejos, Carlos [ (b) (6) FNIH Central Account [ (b) (6) Hallett, Adrienne (NIH/OD) [E] [ (b) (6) ]; Myles, Renate (NIH/OD) [E] [ (b) (6) Wolinetz, Carrie (NIH/OD) [E] [ (b) (6) ]; Appell, Evan [ (b) (6) Sorosa, Alex [ (b) (6) Connelly, Sarah [ (b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Lepore, John [ (b) (6) Pangalos, Mene [ (b) (6) Paul, Steve [ (b) (6) Rasi, Gu do [ (b) (6) Reese, David [ (b) (6) Austin, Sarah (NIH/NIAID) [E] [ (b) (6) Barasch, Kimberly (NIH/NIAID) [C] [ (b) (6) Bell, Julie [ (b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [ (b) (6) Carver, Trea (NIH) [C] [ (b) (6) ; Caulfied, Anita [ (b) (6) Coan, Amanda [ (b) (6) Conrad, Patricia (NIH/NIAID) [E] [ (b) (6) .gov], Dimishkov, Roxanne [ (b) (6) Fuhrer, Nicole [ (b) (6) Giorgi, Sara [ (b) (6) Hoffstetter, Renata (FNIH) [T] [ (b) (6) Iberdemaj, Vaide [ (b) (6) Jenkins, Christine S. [ (b) (6) Lagos, Enrique (NIH/NCATS) [E] [ (b) (6) ]; Lever, Susan [ (b) (6) McManus, Ayanna (NIH/OD) [E] [ (b) (6) Minnich, Beth [ (b) (6) Perala, Mie [mie.pera (b) (6) Protasiewicz, Ann [ (b) (6) Riccobene, Kim [ (b) (6) Riggins, Mary [ (b) (6) Ripley, Nadege [ (b) (6) Schuster, Donna [ (b) (6) Sepulveda, Dorina (FNIH) [T] [ (b) (6) Simon, Dina (NIH/OD) [C] [ (b) (6) ]; Suhana, Tina (NIH/VRC) [E] [ (b) (6) ]; Thomas, Ashley (FDA/CDER) [ (b) (6) Wood, Gretchen (NIH/OD) [E] [ (b) (6) ]; Togashi, Miko (NIH/NCI) [E] [ (b) (6)

[ (b) (6) ]; Underwood, Nancy [ (b) (6) Zottoli, Jessica  
[ (b) (6) Regan, Donna M [ (b) (6) Hamilton, Nancy  
[ (b) (6) Dana Carluccio [ (b) (6)  
[ (b) (6) Lowy, Douglas (NIH/NCI) [E] [ (b) (6) Plenge, Robert  
[ (b) (6) Vessey, Rupert [ (b) (6) Victoria Davey [ (b) (6) ];  
Burklow, John (NIH/OD) [E] [ (b) (6) Harris, Melissa (NIH/OD) [E] [ (b) (6) ]; Kuethe,  
Christine (OS/ASPR/BARDA) (CTR) [ (b) (6) Edl, Susan [ (b) (6) Hoban, Michele  
[ (b) (6)

**Subject:** ACTIV Leadership Call #9

**Location:** <https://fnih.zoom.us/> (b) (6)

**Start:** 10/21/2020 1:15:00 PM

**End:** 10/21/2020 2:15:00 PM

**Show Time As:** Busy

**Required Attendees:** Melencio, Cheryl (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavalen, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Rasi, Guido; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy, Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; Hawk, Harrison; Stratton Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Anderson, James (NIH/OD) [E]; (b) (6)  
Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Appell, Evan; Sorosa, Alex; Connelly, Sarah  
**Optional Attendees:** Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Caulfield, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lagos, Enrique (NIH/NCATS) [E]; Lever, Susan; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Peralta, Mie; Protasiewicz, Ann; Riccobene, Kim; Riggan, Mary; Ripley, Nadege; Schuster, Donna; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieke (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Regan, Donna M; Hamilton, Nancy; Dana Carluccio; (b) (6) Lowy, Douglas (NIH/NCI) [E]; Plenge, Robert; Vessey, Rupert; Davey, Victoria; Burklow, John (NIH/OD) [E] (b) (6) Harris, Melissa (NIH/OD) [E]; Kuethe, Christine (OS/ASPR/BARDA) (CTR)

Due to an unavoidable conflict for Dr. Collins, it is necessary to move this call from 12:00 p.m. to 9:15 a.m. Thank you.

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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**From:** Mascola, John (N H/VRC) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F78B40A596B4CA4A2850A429D1AE3F2-JMASCOLA]  
**Sent:** 5/14/2020 1:02:32 PM  
**To:** Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]  
**CC:** Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]  
**Subject:** RE: ChAdOx1

Francis - we did make good progress on ACTIV Vaccine WG. Yesterday on the vaccine clinical trials subgroup, we presented the harmonized protocol approach and high level details of phase 3 design. There was good input on both and general agreement, with some useful recommendations on efficient ways to conduct phase 3.

One Issues is that the Pfizer representative on the subgroup, both Kathrin Jansen (who is co-chair of Vaccines WG), and Bill Gruber (Pfizer Senior VP for R&D) – took turns articulating their view that large Pharma companies like theirs prefer not to work with USG and it would just slow them down. When we asked for suggestions for DSMB, Kathrin said she did not agree that we should ask for nominations – because this issue required more discussion – mainly because Pfizer has no interest in this. Doug Lowy was on the call, so may be useful to get his perspective.

John

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**From:** Marks, Peter < > (b) (6)  
**Sent:** Thursday, May 14, 2020 6:23 AM  
**To:** Collins, Francis (NIH/OD) [E] < > (b) (6) Mascola, John (NIH/VRC) [E] < > (b) (6) Lane, Cliff (NIH/NIAID) [E] < > (b) (6)  
**Cc:** Fauci, Anthony (NIH/NIAID) [E] < > (b) (6) Wholley, David (FNIH) [T] < > (b) (6) Tabak, Lawrence (NIH/OD) [E] < > (b) (6) Parker, Ashley (NIH/OD) [E] < > (b) (6)  
**Subject:** RE: ChAdOx1

Dear Francis,

We had made good progress with the Oxford AZ team on the clinical end before the contracting period began. From my last conversation with the AZ clinical team they were on board with the USG concept of a large phase 3 trial, potentially as part of a master protocol if the timing was right. Their major issue was getting moving rapidly.

Among other things, Tony, John and I discussed the concept that > (b) (5)  
> (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

Happy to discuss

further.

Best Regards,  
Peter

**From:** Collins, Francis (NIH/OD) [E] (b) (6)

**Sent:** Thursday, May 14, 2020 5:38 AM

**To:** Mascola, John R (NIH) (b) (6) b) (6) Lane, Henry C (NIH) < (b) (6) Marks, Peter  
< (b) (6)

**Cc:** Fauci, Anthony S (NIH) < (b) (6) ; Wholley, David N (NIH) (b) (6) ; Tabak, Lawrence A  
(NIH) < (b) (6) >; Parker, Ashley S (NIH) (b) (6) (6)

**Subject:** ChAdOx1

Gentlemen:

I need to know the update on where we are with Oxford, A-Z, and ChAdOx1. I see there's a BARDA WebEx at 5 pm, and I have a rescheduled phone call this morning with John Bell. I'd like to be as useful as possible in making a plan that includes this vaccine program as part of the harmonized master protocol. Advice about how to use the call with John Bell most effectively would be most welcome!

And did the Vaccines WG make good progress yesterday on the details of the harmonized master protocol? Did they agree in principle to a single DSMB?

Thanks, Francis

APAR0000006226-2517722

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**From:** (b) (6) [ (b) (6)  
**Sent:** 5/18/2020 11:56:42 AM  
**To:** Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Pollock, Rachel (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4887cb3513e242dfa7d2d712dcc6d6a-pollockrc]; Wooldridge, Shannon (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense]  
**Subject:** Re: Time sensitive: Making your ACTIV Participation Public

Hi Renate, Rachel, and Shannon,

We've made lots of progress! Shannon — can we see if the 3 ACTIV participants responded to Dr. Collins privately over the weekend?

Thank you,  
Ashley

On May 17, 2020, at 11:15 PM, Myles, Renate (NIH/OD) [E] (b) (6) wrote:

Hi Ashley and Rachel:

Below are the three people I did not hear from. I searched my inbox. Just wanted to double check that they didn't just respond to Francis. Thanks, Renate

**Ralph Baric, Ph.D.**

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology  
Professor, Department of Microbiology and Immunology  
University of North Carolina, Gillings School of Global Public Health

(b) (6)

**Damon Deming, Ph.D.**

Virologist, Division of Antiviral Products, Office of New Drugs  
U.S. Food and Drug Administration

(b) (6)

**Kathrin Jansen, Ph.D.**

Senior Vice President and Head of Vaccine Research and Development  
Pfizer

(b) (6)

**From:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Sent:** Thursday, May 14, 2020 11:00 AM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6) 6  
**Cc:** Myles, Renate (NIH/OD) [E] (b) (6) >; Meltzer, Abbey (FNIH) [T] (b) (6)  
Wholley, David (FNIH) [T] (b) (6)  
**Subject:** Time sensitive: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.**

Thanks,  
Francis

Francis S. Collins, MD, PhD  
NIH Director

**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
**Sent:** 11/10/2020 7:59:58 PM  
**To:** Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fid]; Draghia-Akli, Ruxandra [ (b) (6) Eisner, Mark [ (b) (6) Gottesdiener, Keith (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [ (b) (6) LaVange, Lisa [ (b) (6) Levy, Elliot [ (b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras], Patel, Naimish [na (b) (6) Peppercorn, Amanda [ (b) (6) Poole, Mike [ (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia Colli]; Amanda Peppercorn [ (b) (6) Garner, Carl (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dc8c847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [ (b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative

Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV DTRA RD (USA) | (b) (6) Petrovick, Martha - 0449 - MITLL | (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy | (b) (6) Jansen, Kathrin | (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John (b) (6) Biggs, Mary | (b) (6) Butcher, Tina | (b) (6) Demarcus | (b) (6) Macone, Erin | (b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7248415bb86087d08b628e6f-melencioc]; Salathin, Carla | (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan (b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio | (b) (6) Rose Li Central Account | (b) (6) Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]. Lucas Smal don [Lucas.Small don@roseliassociates.com]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188]; (b) (6) Mollica, Linda /US | (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c289105913411a3ed28f929042aad-RUBIND.fda]; Marston, H lary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Wung, Peter /US | (b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk], Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) | (b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) | (b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acb5fd03bdfd32930-walkerp1]; Bethany Stokes (b) (6) ]; asorosa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]

Subject: Potential Digital Symposium of Interest to ACTIV TX-Clinical WG



Dear ACTIV TX-Clinical WG Members,

Some of our NIH colleagues felt that you all might be interested in the meeting below. There will be a number of talks that will discuss post-pandemic clinical trial planning and modifications based on lessons that we have learned.

Looking forward to seeing you all Thursday!

Kind regards,  
Stacey

The 17th Global CardioVascular Clinical Trialists (CVCT) Forum from December 3-December 7th, 2020, will be virtual, and we would like to offer this as an opportunity for all NIH clinical trialists to participate and benefit from free registration this year. We hope that you, as an NIH clinical trialist, will appreciate the opportunity to experience the CVCT uniqueness, if you haven't participated in past meetings. Registration will allow you to attend all 45 sessions, listen to over 300 presentations and network and debate virtually with over 250 key trialists LIVE.

CVCT is a unique think tank forum dedicated to clinical trial science in the space of CardioVascular, CardioRenal and Cardiometabolic diseases. It is also the place where critical latest trials, are discussed in depth, individually and in context. Discussion includes understanding trial rationale, design issues, trial conduct and operational issues, statistical methodology and interpretation, clinical meaning, approvability by major regulatory agencies, valuation by payers and implementation in clinical practice.

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Faiez Zannad

Emeritus Professor of Therapeutics and Cardiology Inserm and Université de Lorraine, CHU Nancy, France Founder and Chairman. 17th Global CardioVascular Clinical Trialists Forum December 3 - 7, 2020, Washington D.C.

Stacey J. Adam, PhD

Director, Cancer

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**From:** Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
**Sent:** 4/24/2020 12:33:02 AM  
**To:** Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [ (b) (6) Ke.th Gottesdiener [ (b) (6) Eric Hughes [ (b) (6) LaVange, Lisa M [ (b) (6) Elliott Levy [ (b) (6) Sandeep Menon [ (b) (6) Amanda Peppercorn [ (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [ (b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Far ey, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [ (b) (6)  
**CC:** Mary Biggs [ (b) (6) Demarcus [ (b) (6) Macone, Erin [ (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [ (b) (6) Elizabeth Kim [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [ (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wung, Peter /US [ (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Stratton, Benjamin [ (b) (6)  
**Subject:** ACTIV TX-Clinical Master Protocol Subgroup Meeting #7  
**Attachments:** ACTIV Therapeutics-Clinical\_MP Subgroup 24Apr2020 Meeting Guide.pdf; ACTIV Therapeutics Clinical Master Protocol Sub-Group Meeting #7 Agenda\_04222020.pdf; Drug-info-COVID-19-Visante-4-21.pdf; ACTIV\_Therapeutics-Clinical\_MP Sub-Group Meeting 6\_Key Takeaways\_04232020.pdf  
**Location:** https://fnih.zoom. (b) (6)  
**Start:** 4/24/2020 2:00:00 PM  
**End:** 4/24/2020 3:00:00 PM  
**Show Time As:** Tentative

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**Required Attendees:** Bozzette, Sam (NIH/NCATS) [E]; Joan Butters; Collins, Sylvia (FDA/CDER); Judy Currier; De Caro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes, Lisa LaVange, Elliott Levy; Sandeep Menon, Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER), Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael

**Optional Attendees:** Mary Biggs, Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Wung, Peter /US; Qashu, Felicia (NIH/OD) [E]; Stratton, Benjamin

Dear TX-Clinical Master Protocol Subgroup,

Please find attached the materials for tomorrow's meeting.

1. Agenda
2. Slides for discussion updated with the decisions from today
3. A useful resource about current standard clinical treatment guidelines from the front lines for COVID. This may be a useful resource in selecting how to do minimal data collection and trying to understand SOC.
4. Notes from Meeting 6

Please let me know if you have questions or other things you think would be helpful for the group to review.

Thanks,  
Stacey

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**From:** Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]  
**Sent:** 5/6/2020 12:55:17 AM  
**To:** Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]  
**Subject:** RE: news and question

From what I hear it is likely good news. J&J is willing to put the trial they were planning for infliximab (Remicade), one of the immune modulators the Tx-Clinical Agent Prioritization Sub Group has put near the top of their list for ACTIV, on hold despite its being well through planning with FDA, in favor of putting it into the "ACTIV ACTT-3" protocol we are proposing to launch. She has discussed it with Mattai Mammen who makes these kinds of decisions. Don't know whether Paul Stoffels has been told yet. So what I strongly recommend you do: take the call, play dumb, and be absolutely delighted.

(Hope that is indeed what this turns out to be!)

**From:** Collins, Francis (NIH/OD) [E] < > (b) (6)  
**Sent:** Tuesday, May 5, 2020 7:30 PM  
**To:** Wholley, David (FNIH) [T] < > (b) (6)  
**Subject:** FW: news and question  
**Importance:** High

Any idea what this might be about?

**From:** Draghia Akli, Ruxandra [JRDUS] (b)  
**Sent:** Tuesday, May 5, 2020 6:14 PM  
**To:** Collins, Francis (NIH/OD) [E] < > (b) (6)  
**Subject:** news and question  
**Importance:** High

Dear Francis – this world is getting smaller ☺ it is really great to be able to join forces on COVID. Another example of "all hands on deck" and undertaking something meaningful, with a tremendous impact on global health.

Would it be possible to have a short chat rapidly? I do have some news, and would like to get your feedback, if possible.

Kind regards, Rux

Ruxandra Draghia-Akli, MD, PhD  
Global Head  
Global Public Health R&D



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Sincerely,  
[Signature]



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 (b) (6) Lowy, Douglas (NIH/NCI) [E] [ (b) (6) ]; (b) (6)  
 Arvin, Ann [ (b) (6) (b) (6) Cavaleri Marco [ (b) (6) (b) (6)  
 (b) (6) mmdavis [ (b) (6) (b) (6) Greg Glenn  
 [ (b) (6) (b) (6) Haynes, Barton [ (b) (6) (b) (6)  
 (b) (6) Marks, Peter (FDA/CBER) [ (b) (6) Mascola, John (NIH/VRC) [E]  
 (b) (6) Messonnier, Nancy (CDC/DDID/NCIRD/OD) [ (b) (6) Nelson Michael  
 [ (b) (6) Offit, Paul [ (b) (6) (b) (6) Seals, Jonathan  
 (OS/ASPR/BARDA) [ (b) (6) (b) (6) (b) (6) Tal Zaks  
 [ (b) (6) Beth Bell [ (b) (6) [ (b) (6)  
**CC:** btolman [ (b) (6) (b) (6) Hopps, Markay [ (b) (6)  
 Kozlowski, Mary (NIH/NCI) [C] [ (b) (6) Johnson, Maureen (NIH/NCI) [E]  
 (b) (6) (b) (6) Jeneffer Haynes [ (b) (6)  
 (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E]  
 [ (b) (6) .gov]; (b) (6) Isabel Ramsey [ (b) (6) Parker,  
 Ashley (NIH/OD) [E] [ (b) (6) Marston, Hilary (NIH/NIAID) [E] [ (b) (6) ]; Erbeling,  
 Emily (NIH/NIAID) [E] [ (b) (6) Dieffenbach, Carl (NIH/NIAID) [E] [ (b) (6)  
 Qashu, Felicia (NIH/OD) [E] [felicia. (b) (6) Culp, Michelle (NIH/OD) [E] [ (b) (6) Gadbois,  
 Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Wholley, David (FNIH) [T]  
 [ (b) (6) Melencio, Cheryl (FNIH) [T] [ (b) (6) Menetski, Joseph (FNIH) [T]  
 (b) (6) Adam, Stacey (FNIH) [T] [ (b) (6) Tountas, Karen (FNIH) [T] [ (b) (6)  
 James, Stephanie (FNIH) [T] [ (b) (6) Colvis, Christine (NIH/NCATS) [E] [ (b) (6)  
 Desrosiers, Betsy [ (b) (6) Eric Hughes [ (b) (6) Kurilla, Michael  
 (NIH/NCATS) [E] [ (b) (6) Read, Sarah (NIH/NIAID) [E] [ (b) (6) Paul Gillard  
 [ (b) (6) François P Roman [ (b) (6) Hamilton, Holli (OS/ASPR/BARDA)  
 (b) (6) Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA)  
 [ (b) (6) Kathleen Neuzil [ (b) (6) Martin, Stacey  
 (CDC/DDID/NCEZID/DVBD) [ (b) (6) McNamara, Lucy Alexandra (CDC/DDID/NCIRD/DBD) [ (b) (6) ]  
 Goldstein, Jason (CDC/DDID/NCEZID/DSR) [ (b) (6) Schrag, Stephanie (CDC/DDID/NCIRD/DBD)  
 [ (b) (6) Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) [ (b) (6) Lindsey, Nicole  
 (CDC/DDID/NCEZID/DVBD) [ (b) (6) Thornburg, Natalie (CDC/DDID/NCIRD/DVD) [ (b) (6) ]; Wachtel,  
 Jonathan' (b) (6) Stratton, Benjamin [ (b) (6) Margaret Anderson  
 [ (b) (6) (b) (6) (b) (6) Bethany Stokes  
 [ (b) (6) Kathleen Callahan [ (b) (6) Molloy, Delia (DPH)  
 [ (b) (6) Wood, Gretchen (NIH/OD) [E] [ (b) (6) Filip Dubovsky  
 [ (b) (6) ]; Michael Watson (x) [ (b) (6) Jacqueline Miller  
 [ (b) (6) Antonio Lanzavecchia [ (b) (6) Arvin, Ann  
 [ (b) (6) Harris, Rebecca /SG (b) (6) ; Vivek Shinde [ (b) (6)  
 Cohen, Myron [ (b) (6) Criffield, Robin R. [ (b) (6) Marovich, Mary  
 (NIH/NIAID) [E] [ (b) (6) FNIH [ (b) (6) Barton Haynes, M.D.  
 [barton. (b) (6) Michael, Nelson [ (b) (6) Brown ScD, Elizabeth R  
 [ (b) (6) Pettifor, Audrey E [ (b) (6) Janes PhD, Holly E [ (b) (6)  
 Stephenson, Kathryn (HMFP - Vaccine Research) [ (b) (6) Najaf Shah [ (b) (6) ];  
 Young, John (b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]

**Subject:** ACTIV Vaccines Working Group meeting

**Location:** <https://fnih.zoom.us> (b) (6)

**Start:** 12/14/2020 5:00:00 PM

**End:** 12/14/2020 6:00:00 PM

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**Required Attendees:** Santos, Michael (FNIH) [T]; (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6) Arvin, Ann; Beth Bell (b) (6) (b) (6) Cavaleri Marco; (b) (6) (b) (6) Barton; (b) (6) (b) (6) Greg Glenn; (b) (6) Haynes, Messonnier, Nancy (CDC/DDID/NCIRD/OD); Nelson Michael; Offit, Paul; (b) (6) Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E]; (OS/ASPR/BARDA); (b) (6) (b) (6) ; Tal Zaks

**Optional Attendees:** Tolman, Brett; (b) (6) Hopps, Markay; Kozlowsk, Mary (NIH/NCI) [C]; Johnson Maureen (NIH/NCI) [E]; (b) (6) Jeneffer Haynes; (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E]; (b) (6) Isabel Ramsey; Parker, Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Erbeling, Emily (NIH/NIAID) [E]; Dieffenbach, Carl (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Elen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul Gillard; François P Roman; Hamilton, Holli (OS/ASPR/BARDA); Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA); Kathleen Neuzil; Martin, Stacey (CDC/DDID/NCEZID/DVBD); McNamara, Lucy Alexandra (CDC/DDID/NCIRD/DBD); Goldstein, Jason (CDC/DDID/NCEZID/DSR); Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Lindsey, Nicole (CDC/DDID/NCEZID/DVBD); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin; Anderson, Margaret; (b) (6) (b) (6) Bethany Stokes; Kathleen Callahan; Molloy, Delia (DPH); Wood, Gretchen (NIH/OD) [E]; Filip Dubovsky; Michael Watson (x); Jacqueline Miller; Antonio Lanzavecchia; Ann Arvin; Harris, Rebecca /SG; Vivek Shinde; Cohen, Myron; Criffield, Robin R.; Marovich, Mary (NIH/NIAID) [E]; FNIH; Barton Haynes, M.D.; Nelson Michael; Brown ScD, Elizabeth R; Pettifor, Audrey E; Janes PhD, Holly E; Stephenson, Kathryn (HMFP - Vaccine Research); Najaf Shah

Michael Santos is inviting you to a scheduled Zoom meeting.

Topic: ACTIV Vaccines Working Group meeting

Time: Dec 14, 2020 12:00 PM Eastern Time (US and Canada)

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**From:** Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]  
**Sent:** 8/28/2020 12:48:37 PM  
**To:** George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]  
**Subject:** FW: Materials for August 26 ACTIV Partnership Leadersh p Team Teleconference  
**Attachments:** 8.26 ACTIV Leadership Team Meeting 20200825 vFinal.pdf; 2020-07-29 ACTIV Leadership Team Meeting Summary final.pdf; 2020-08-14 Executive Committee Meeting Summary vFinal.pdf

**From:** Melencio, Cheryl (FNIH) [T] < (b) (6) > **On Behalf Of** Wholley, David (FNIH) [T]  
**Sent:** Tuesday, August 25, 2020 9:47 PM  
**To:** Austin, Christopher (NIH/NCATS) [E] < (b) (6) > Bancel, Stephane  
< (b) (6) > Carter, Kara < (b) (6) > Cavaleri, Marco  
< (b) (6) > Cihlar, Tomas < (b) (6) > Collins, Francis (NIH/OD) [E]  
< (b) (6) > Corey, Larry < (b) (6) > Culp, Michelle (NIH/OD) [E] < (b) (6) >  
Disbrow, Gary (OS/ASPR/BARDA) < (b) (6) > Dolsten, Mikael < (b) (6) > Erbeling, Emily (NIH/NIAID) [E] < (b) (6) > Erck, Stan < (b) (6) > Fauci, Anthony (NIH/NIAID) [E]  
< (b) (6) > Freire, Maria (FNIH) [T] < (b) (6) > Gadbois, Ellen (NIH/OD) [E]  
< (b) (6) > Gibbons, Gary (NIH/NHLBI) [E] < (b) (6) > Hudson, Thomas  
< (b) (6) > James, Stephanie (FNIH) [T] < (b) (6) > Johnson, Robert (OS/ASPR/BARDA)  
< (b) (6) > Kramer, Lynn < (b) (6) > Lane, Cliff (NIH/NIAID) [E] < (b) (6) >  
Lepore, John < (b) (6) > Marks, Peter (FDA/CBER) < (b) (6) > Marston, Hilary (NIH/NIAID) [E] < (b) (6) > Mascola, John (NIH/VRC) [E] < (b) (6) > Meeker, David  
< (b) (6) > Menetski, Joseph (FNIH) [T] < (b) (6) > Messonnier, Nancy  
(CDC/DDID/NCIRD/OD) < (b) (6) > Pandya, Hitesh < (b) (6) > Pangalos, Mene  
< (b) (6) > Pao, William < (b) (6) > Parker, Ashley (NIH/OD) [E]  
< (b) (6) > Paul, Steve < (b) (6) > Perlmutter, Roger < (b) (6) >  
Plenge, Robert < (b) (6) > Plump, Andy < (b) (6) > Rachel Ramoni  
< (b) (6) > Rasi, Guido < (b) (6) > Reed, John < (b) (6) > Reese, David  
< (b) (6) > Rouse, Doris < (b) (6) > Santos, Michael (FNIH) [T] < (b) (6) > Skovronsky, Daniel < (b) (6) > Stein, Peter (FDA/CDER) < (b) (6) > Stoffels, Paul  
< (b) (6) > Tabak, Lawrence (NIH/OD) [E] < (b) (6) > Talley, Michael  
< (b) (6) > Tsai, John < (b) (6) > Vessey, Rupert < (b) (6) > Virgin, Skip  
< (b) (6) > Wholley, David (FNIH) [T] < (b) (6) > Woodcock, Janet (FDA/CDER)  
< (b) (6) > Young, John < (b) (6) > Colvis, Christine (NIH/NCATS) [E]  
< (b) (6) > Desrosiers, Betsy < (b) (6) > Eric Hughes  
< (b) (6) > Jansen, Kathrin < (b) (6) > Kurilla, Michael (NIH/NCATS) [E]  
< (b) (6) > Lowy, Douglas (NCI) < (b) (6) > Read, Sarah (NIH/NIAID) [E] < (b) (6) >  
Young, John < (b) (6) >  
**Cc:** Adam, Stacey (FNIH) [T] < (b) (6) > Alvarez, Rosa < (b) (6) > Anderson, Margaret  
< (b) (6) > Chen, Helen < (b) (6) > Elsaid, Olivia < (b) (6) >  
Gonzalez, Nina < (b) (6) > Hawk, Harrison < (b) (6) > Menetski, Joseph (FNIH) [T]  
< (b) (6) > Santos, Michael (FNIH) [T] < (b) (6) > Stratton, Benjamin < (b) (6) >  
btolman < (b) (6) > Tountas, Karen (FNIH) [T] < (b) (6) > Wachtel, Jonathan  
< (b) (6) > Wholley, David (FNIH) [T] < (b) (6) > Anderson, James (NIH/OD) [E]  
< (b) (6) > Austin, Christopher (NIH/NCATS) [E] < (b) (6) > Burklow, John (NIH/OD) [E]  
< (b) (6) > Castillejos, Carlos < (b) (6) > Culp, Michelle (NIH/OD) [E]  
< (b) (6) > FNIH Central Account < (b) (6) > Freire, Maria (FNIH) [T]  
< (b) (6) > Gadbois, Ellen (NIH/OD) [E] < (b) (6) > Hallett, Adrienne (NIH/OD) [E]

< (b) (6) Lane, Cliff (NIH/NIAID) [E] < (b) (6) Myles, Renate (NIH/OD) [E]  
 < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Tabak, Lawrence (NIH/OD) [E]  
 < (b) (6) Wolinetz, Carrie (NIH/OD) [E] < (b) (6) Burklow, John (NIH/OD) [E]  
 < (b) (6) Gorman, Greta (FNIH) [T] < (b) (6) Hallett, Adrienne (NIH/OD) [E]  
 < (b) (6) Meltzer, Abbey (FNIH) [T] < (b) (6) Myles, Renate (NIH/OD) [E]  
 < (b) (6) Wolinetz, Carrie (NIH/OD) [E] < (b) (6) Lucas Smalldon  
 < (b) (6) Villafana, Tonya < (b) (6) Brian Rosen  
 < (b) (6)

**Subject:** Materials for August 26 ACTIV Partnership Leadership Team Teleconference

**Importance:** High

Dear Colleagues:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from 3:00 – 4:00 PM Eastern U.S. time tomorrow, Wednesday August 26. (As a reminder, this meeting and future LT meetings are 60 minutes in length.) I have also attached notes from our July 29 Leadership Team meeting as well as our last ACTIV EC meeting on August 14.

The Zoom meeting information is:

Join Zoom Meeting

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 US (Houston)  
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Meeting ID: (b) (6)

Passcode: (b) (6)

Find your local number: <https://fnih.zoom.us> (b) (6)

Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley  
Senior Vice-President, Research Partnerships  
Foundation for the National Institutes of Health  
(b) (6)

[fnih.org](https://fnih.org)  
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

*In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.*





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**Required Attendees:** Jim Neaton; Jens Lundgren; Read, Sarah (NIH/NIAID) [E]; Eric Hughes, Higgs, Elizabeth (NIH/NIAID) [E]; Srinivasan, Badhri; Goff, David (NIH/NHLBI) [E]; Nayak, Seema (NIH/NIAID) [E]; Victoria Davey; Kozak, Marina (OS/ASPR/BARDA); McNay, Laura (NIH/NIAID) [E]; Tierney, John (NIH/NIAID) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Patterson, Amy (NIH/NHLBI) [E]; Miller, Marissa A (NIH/NHLBI) [E]; Rachel Harrigan; William Erhardt; Reineck, Lora (NIH/NHLBI) [E], (b) (6) Gelijns, Annetine, Mark Polizzotto; Ginny Kan; Baker, Jason; Roger Paredes; Thompson, Taylor, M.D.; Babiker, Ab

**Optional Attendees:** Chen, Helen Q.; Wachtel, Jonathan; Tountas, Karen (FNIH) [T]; Desrosiers, Elizabeth A.; Kurilla, Michael (NIH/NCATS) [E]; Kenny, Dermot; Parker, Ashley (NIH/OD) [E]; Pett, Sarah; Grace, Beth (NIH/NIAID) [C]; Barrett, Kevin (NIH/NIAID) [E]; Denning, Eileen; Eileen Denning

Dear ACTIV-3 Operations Team,

Please find attached the agenda for tomorrow's meeting. If you have any additions or amendments, please let me know.

Jens or others, if you have slides that you would like me to pre-distribute, send them to me and I will get them out.

Thanks,  
Stacey

Join Zoom Meeting

<https://fnih.zoom.us/j/9121111111>

(b) (6)

Meeting ID: (b) (6)

Password: (b) (6)

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US (New York)

US (San Jose)

US (Tacoma)

US (Houston)

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Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://fnih.zoom.us/j/9121111111> (b) (6)

Sent: 9/9/2020 6:52:10 PM  
To: Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]  
Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting

-----Original Message-----

From: Patterson, Amy (NIH/NHLBI) [E] <(b) (6)>  
Sent: Wednesday, September 9, 2020 2:50 PM  
To: Chen, Helen Q. <(b) (6)>; Adam, Stacey (FNIH) [T] <(b) (6)> Bozzette, Sam  
(NIH/NCATS) [E] <(b) (6)> Butterson, Joan <(b) (6)> De Claro, R. Angelo  
(FDA/CDER) <(b) (6)> Draghia-Akli, Ruxandra <(b) (6)> Eisner, Mark  
<(b) (6)> Gottesdiener, Keith <(b) (6)> Eric Hughes  
<(b) (6)> Judy Currier <(b) (6)> Kim, Elizabeth  
<(b) (6)> LaVange, Lisa <(b) (6)> Levv, Elliot <(b) (6)> Mellors,  
John W <(b) (6)> Menon, Sandeep <(b) (6)> >; Parker, Ashley (NIH/OD) [E]  
<(b) (6)> Patel, Naimish <(b) (6)> Peppercorn, Amanda  
<(b) (6)> Poole, Mike <(b) (6)> Proschan, Michael  
(NIH/NIAID) [E] <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)> Santos,  
Michael (FNIH) [T] <(b) (6)> Shen, Yuan Li (FDA/CDER) <(b) (6)> Stein, Peter  
(FDA/CDER) <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Buchman, Tim  
(OS/ASPR/BARDA) (CTR) <(b) (6)> Collins, Sylva (FDA/CDER) <(b) (6)> Higgs,  
Amanda Peppercorn <(b) (6)> Garner, Carl <(b) (6)> Koroshetz, Walter (NIH/NINDS) [E]  
Elizabeth (NIH/NIAID) [E] <(b) (6)> Timothy Burgess <(b) (6)> Reineck, Lora (NIH/NHLBI) [E]  
<(b) (6)> Aggarwal, Neil (NIH/NHLBI) [E] <(b) (6)> Rosenberg, Yves  
(NIH/NHLBI) [E] <(b) (6)> Goff, David (NIH/NHLBI) [E] <(b) (6)> Brown, Jeremy  
(NIH/NINDS) [E] <(b) (6)> Gadbois, Ellen (NIH/OD) [E] <(b) (6)> Culp,  
Michelle (NIH/OD) [E] <(b) (6)> Jacqueline Kirchner  
<(b) (6)> Beigel, John (NIH) [E] <(b) (6)> >; Phillips, L  
Revell CIV DTRA RD (USA) <(b) (6)> Petrovick, Martha - 0449 - MITLL  
<(b) (6)> Sizemore, Christine (NIH/FIC) [E]  
<ch <(b) (6)>  
Cc: Colvis, Christine (NIH/NCATS) [E] <(b) (6)> Desrosiers, Betsy  
<(b) (6)> Jansen, Kathrin <(b) (6)> Kurilla, Michael  
(NIH/NCATS) [E] <(b) (6)> Lowy, Douglas (NCI) <(b) (6)> >; Young, John  
<(b) (6)> Biggs, Mary <(b) (6)> Butcher, Tina <(b) (6)>  
Demarcus <(b) (6)> Macone, Erin <(b) (6)> Melencio, Cheryl (FNIH) [T]  
<(b) (6)> Salathin, Carla <(b) (6)> Tountas, Karen (FNIH) [T]  
<(b) (6)> Menetski, Joseph (FNIH) [T] <menetski@tnih.org>; James, Stephanie (FNIH) [T]  
<(b) (6)> Wachtel, Jonathan <(b) (6)> btolman <(b) (6)> Alvarez,  
Rosa Maria <(b) (6)> Gonzalez, Nina <(b) (6)> Dana Carluccio  
<dana.car <(b) (6)>; Rose Li Central Account <(b) (6)> Margaret  
Anderson <(b) (6)> Lucas Smalldon <(b) (6)> Stratton,  
Benjamin <(b) (6)> Jennifer, J. <(b) (6)> Mollica, Linda /JS  
<Linda.Mol <(b) (6)> Oashu, Felicia (NIH/OD) [E] <(b) (6)> Rubin, Daniel B.  
(FDA/CDER) <(b) (6)> .gov>; Marston, Hilary (NIH/NIAID) [E] <(b) (6)> Wung,  
Peter /US <(b) (6)> Hoots, W. Keith (NIH/NHLBI) [E] <(b) (6)> Groesch, Mary  
(NIH/NHLBI) [E] <(b) (6)> Shidd, Allan (NIH/NHLBI) [E] <(b) (6)> Kindzelski,  
Andrei (NIH/NHLBI) [E] <(b) (6)> >; Hone, David M (Dave) CIV DTRA J9 (USA)  
<(b) (6)> Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA)  
<(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)> Elsaid, Olivia  
<(b) (6)> Appell, Evan <(b) (6)>  
Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting

Hi Helen,  
Thanks for developing this helpful chart. Two of the NHLBI trials are not on the chart - will try to send you the info later today.  
Amy

-----Original Message-----

From: Chen, Helen Q. <(b) (6)>  
Sent: Wednesday, September 9, 2020 1:27 PM  
To: Adam, Stacey (FNIH) [T] <(b) (6)> Bozzette, Sam (NIH/NCATS) [E] <(b) (6)>  
Butterson, Joan <(b) (6)> De Claro, R. Angelo (FDA/CDER) <(b) (6)>  
Draghia-Akli, Ruxandra <(b) (6)> Eisner, Mark <(b) (6)> Gottesdiener, Keith  
<(b) (6)> Eric Hughes <(b) (6)> Judy Currier  
<(b) (6)> Kim, Elizabeth <(b) (6)> LaVange, Lisa <(b) (6)>  
<(b) (6)> Levv, Elliot <(b) (6)> Mellors, John W <(b) (6)> Menon, Sandeep  
<(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Patel, Naimish  
<(b) (6)> Peppercorn, Amanda <(b) (6)> Poole, Mike

< (b) (6) Proschan, Michael (NIH/NIAID) [E] < (b) (6) Read, Sarah  
 (NIH/NIAID) [E] < (b) (6) Santos, Michael (FNIH) [T] < (b) (6) Shen, Yuan Li  
 (FDA/CDER) < (b) (6) Stein, Peter (FDA/CDER) < (b) (6) Wholley, David  
 (FNIH) [T] < (b) (6) Buchman, Tim (OS/ASPR/BARDA) (CTR) < (b) (6) Collins, Sylva  
 (FDA/CDER) < (b) (6) Amanda Peppercorn < (b) (6) Garner, Carl  
 < (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] < (b) (6) Koroshetz, Walter  
 (NIH/NINDS) [E] < (b) (6) .gov; Timothy Burgess < (b) (6) Reineck, Lora  
 (NIH/NHLBI) [E] < (b) (6) Aggarwal, Neil (NIH/NHLBI) [E] < (b) (6)  
 Rosenberg, Yves (NIH/NHLBI) [E] < (b) (6) Goff, David (NIH/NHLBI) [E]  
 < (b) (6) >: Brown, Jeremy (NIH/NINDS) [E] < (b) (6) Gadbois, Ellen (NIH/OD) [E]  
 < (b) (6) Culp, Michelle (NIH/OD) [E] < (b) (6) Jacqueline Kirchner  
 < (b) (6) Beidel, John (NIH) [E] < (b) (6) Phillips, L  
 Revell CIV DTRA RD (USA) < (b) (6) Petrovick, Martha - 0449 - MITLL  
 < (b) (6) Sizemore, Christine (NIH/FIC) [E]  
 < (b) (6)  
 Cc: Colvis, Christine (NIH/NCATS) [E] < (b) (6) Desrosiers, Betsy  
 < (b) (6) Jansen, Kathrin < (b) (6) Kurilla, Michael  
 (NIH/NCATS) [E] < (b) (6) Lowy, Douglas (NCI) < (b) (6) Young, John  
 < (b) (6) Biggs, Mary < (b) (6) Butcher, Tina < (b) (6)  
 Demarcus < (b) (6) Macone, Erin < (b) (6) Melencio, Cheryl (FNIH) [T]  
 < (b) (6) Salathin, Carla < (b) (6) Tountas, Karen (FNIH) [T]  
 < (b) (6) Menetski, Joseph (FNIH) [T] < (b) (6) James, Stephanie (FNIH) [T]  
 < (b) (6) Wachtel, Jonathan < (b) (6) Tolman < (b) (6) Alvarez,  
 Rosa Maria < (b) (6) Gonzalez, Nina < (b) (6) Dana Carluccio  
 < (b) (6) Rose Li Central Account < (b) (6) Margaret  
 Anderson < (b) (6) Lucas Smalldon < (b) (6) Stratton,  
 Benjamin < (b) (6) Mollica, Linda /US  
 < (b) (6) Qashu, Felicia (NIH/OD) [E] < (b) (6) Patterson, Amy  
 (NIH/NHLBI) [E] < (b) (6) Rubin, Daniel B. (FDA/CDER) < (b) (6) Marston,  
 Hilary (NIH/NIAID) [E] < (b) (6) Wung, Peter /US < (b) (6) Hoots, W. Keith  
 (NIH/NHLBI) [E] < (b) (6) Groesch, Mary (NIH/NHLBI) [E] < (b) (6) Shipp,  
 Allan (NIH/NHLBI) [E] < (b) (6) Kindzelski, Andrei (NIH/NHLBI) [E]  
 < (b) (6) Hone, David M (Dave) CIV DTRA J9 (USA) < (b) (6)  
 Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) < (b) (6) Freire, Maria (FNIH)  
 [T] < (b) (6) Elsaid, Olivia < (b) (6) Appell, Evan < (b) (6)  
 Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting

Dear ACTIV TX-Clinical Working Group Members,

As we have discussed previously, NIH has developed a table to summarize ACTIV and other NIH-supported COVID-19 trials. The goal of the table is to be informative to ACTIV and NIH leadership and to be shared more broadly once the information within it is public.

We would appreciate your review of this draft version of the table, which we are sharing ahead of tomorrow's Working Group meeting. Please do not share the table or the information in it further. We are looking forward to your input.

Warm regards,  
Stacey, Mike, and Helen

-----Original Appointment-----

From: Adam, Stacey (FNIH) [T] < (b) (6)  
 Sent: Wednesday, June 17, 2020 8:48 AM  
 To: Adam, Stacey (FNIH) [T]; Bozette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo  
 (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim,  
 Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John W; Menon, Sandeep; Parker, Ashley (NIH/OD) [E];  
 Patel, Narmish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah  
 (NIH/NIAID) [E]; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley,  
 David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn;  
 Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess;  
 Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff,  
 David (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle  
 (NIH/OD) [E]; Jacqueline Kirchner; Beidel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA);  
 Petrovick, Martha - 0449 - MITLL; (b) (6) Sizemore, Christine (NIH/FIC) [E]  
 Cc: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS)  
 [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio,  
 Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James,  
 Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa Maria; Gonzalez, Nina; Dana  
 Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin;  
 (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI)  
 [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US;  
 Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski,  
 Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO  
 CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia  
 Subject: ACTIV Therapeutics-Clinical Working Group Meeting  
 When: Thursday, September 10, 2020 1:00 PM 2:00 PM (UTC 05:00) Eastern Time (US & Canada).  
 Where: <https://fnih.zoom.us>, (b) (6)

Stacey Adam is inviting you to a scheduled Zoom meeting.

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US (New York)

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US (Houston)

US (San Jose)

US (San Jose)

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: [https://fnih.zoom.us/j/\(b\)\(6\)](https://fnih.zoom.us/j/(b)(6)) This message (including any attachments) contains confidential information intended for a specific individual and purpose, and is protected by law. If you are not the intended recipient, you should delete this message and any disclosure, copying, or distribution of this message, or the taking of any action based on it, by you is strictly prohibited.

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v.E.1

**From:** Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]  
**Sent:** 6/8/2020 2:48:03 PM  
**To:** Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; melanie.savill (b) (6)  
(b) (6) Lowy, Douglas (NIH/NCI) [E] [ (b) (6) ]; (b) (6)  
Arvin, Ann [ (b) (6) Beth Bell [ (b) (6) [ (b) (6)  
(b) (6) Cavaleri Marco [ (b) (6) (b) (6)  
(b) (6) (b) (6) Greg Glenn [ (b) (6)  
(b) (6) Haynes, Barton [ (b) (6) (b) (6) (b) (6)  
Marks, Peter (FDA/CBER) [ (b) (6) Mascola, John (NIH/VRC) [E] [ (b) (6)  
Messonnier, Nancy (CDC/DDID/NCIRD/OD) [ (b) (6) Nelson Michael [ (b) (6)  
Offit, Paul [ (b) (6) (b) (6) Seals, Jonathan (OS/ASPR/BARDA)  
[ (b) (6) (b) (6) (b) (6) Tal Zaks  
[ (b) (6) (b) (6) (b) (6) (b) (6)  
(b) (6) (b) (6) (b) (6)  
**CC:** Tolman, Brett [ (b) (6) (b) (6) Hopps, Markay [ (b) (6)  
Kozlowski, Mary (NIH/NCI) [C] [ (b) (6) Johnson, Maureen (NIH/NCI) [E]  
[ (b) (6) (b) (6) Jeneffer Haynes [ (b) (6)  
(b) (6) (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E]  
[ (b) (6) (b) (6) Isabel Ramsey [ (b) (6) Parker,  
Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Marston, Henry  
(NIH/NIAID) [E] [ (b) (6) Qashu, Felicia (NIH/OD) [E] [ (b) (6) Culp, Michelle  
(NIH/OD) [E] [ (b) (6) Gadbois, Ellen (NIH/OD) [E] [ (b) (6) Wholley, David (FNIH) [T]  
[ (b) (6) Melencio, Cheryl (FNIH) [T] [ (b) (6) Menetski, Joseph (FNIH) [T]  
[ (b) (6) Adam, Stacey (FNIH) [T] [ (b) (6) Tountas, Karen (FNIH) [T] [ (b) (6)  
James, Stephanie (FNIH) [T] [ (b) (6) Colvis, Christine (NIH/NCATS) [E] [ (b) (6)  
Desrosiers, Betsy [ (b) (6) Hughes, Eric [ (b) (6) Kurilla, Michael  
(NIH/NCATS) [E] [ (b) (6) Read, Sarah (NIH/NIAID) [E] [ (b) (6) Young, John  
[ (b) (6) Paul Gillard [ (b) (6) Hamilton, Holli (OS/ASPR/BARDA)  
[ (b) (6) Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA)  
[ (b) (6) Kathleen Neuzil [ (b) (6) Schrag, Stephanie  
(CDC/DDID/NCIRD/DBD) [ (b) (6) Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) [ (b) (6)  
Thornburg, Natalie (CDC/DDID/NCIRD/DVD) [ (b) (6) Gonzalez, Nina [ (b) (6) 'Wachtel,  
Jonathan' [ (b) (6) Stratton, Benjamin [ (b) (6) (b) (6)  
(b) (6) Bethany Stokes [ (b) (6) Kathleen Callahan  
[ (b) (6) Kayvon Modjarrad [ (b) (6) Arvin, Ann [ (b) (6)  
Anderson, Margaret [ (b) (6)

**Subject:** ACTIV Vaccines Working Group meeting

**Location:** Webex: <https://nih.webex.com> (b) (6)

**Start:** 6/24/2020 3:00:00 PM

**End:** 6/24/2020 4:00:00 PM

**Show Time As:** Busy

**Required Attendees:** (b) (6) (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6)  
Arvin, Ann; Beth Bell [ (b) (6) (b) (6) Cavaleri Marco; (b) (6)  
(b) (6) (b) (6) Greg Glenn; (b) (6) Haynes,  
Barton; (b) (6) (b) (6) Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E];  
Messonnier, Nancy (CDC/DDID/NCIRD/OD); Nelson Michael; Offit, Paul; (b) (6) Seals, Jonathan  
(OS/ASPR/BARDA); (b) (6) (b) (6) Tal Zaks; (b) (6)  
(b) (6) ) (b) (6) (b) (6) (b) (6) (b) (6)  
(b) (6)

**Optional Attendees:** Tolman, Brett; Jessica. (b) (6) Hopps, Markay; Kozlowsk , Mary (NIH/NCI) [C]; Johnson, Maureen (NIH/NCI) [E]; (b) (6) Jeneffer Haynes; (b) (6) (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E]; (b) (6) Isabel Ramsey; Parker, Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E], Qashu, Felicia (NIH/OD) [E]; Culp, M chelle (NIH/OD) [E], Gadbois, El en (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T], James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy, Hughes, Eric; Kunlla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul Gillard; Hamilton, Holli (OS/ASPR/BARDA); Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA); Kathleen Neuzil; Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jenn fer R. (CDC/DDID/NCIRD/DBD); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin; Anderson, Margaret; (b) (6) (b) (6) ; Bethany Stokes; Kathleen Callahan; Kayvon Modjarrad; Arvin, Ann

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**From:** Melencio, Cheryl (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=279E14FA74284158B86087D08B628E6F-MELENCIOC]  
**on behalf of** Wholley, David (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]  
**Sent:** 12/18/2020 10:39:59 PM  
**To:** Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Bancel, Stephane [ (b) (6) Carter, Kara [ (b) (6) Cavaleri, Marco [ (b) (6) Cihlar, Tomas [ (b) (6) Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [ (b) (6) Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Victoria Davey [ (b) (6) Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Do sten, Mikael [ (b) (6) Erbeling, Emily (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeling]; Erck, Stan [ (b) (6) Fauci, Anthony (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Hudson, Thomas [ (b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn [ (b) (6) Lane, Cliff (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Lepore, John [ (b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Marston, Hilary (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Meeker, David [ (b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Pandya, Hitesh [ (b) (6) Pangalos, Mene [ (b) (6) Pao, William [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Paul, Steve [ (b) (6) Perlmutter, Roger [ (b) (6) Plenge, Robert [ (b) (6) Plump, Andy [ (b) (6) Rachel Ramon [ (b) (6) Rouse, Doris [ (b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel [ (b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul [ (b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Tal ey, Michael [ (b) (6) Tsai, John [ (b) (6) Vessey, Rupert [ (b) (6) ]; Virgin,

Skip [ (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet  
 (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 [ (b) (6) Villafana, Tonya [ (b) (6)  
 CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 [ (b) (6) Castillejos, Carlos [ (b) (6) Culp, Michelle (NIH/OD) [E]  
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 [ (b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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**Subject:** Notes from Wednesday's ACTIV Leadership Team Meeting

**Attachments:** 2020-12-16\_ACTIV Leadership Team and Executive Committee Meeting Summary\_vf.docx

Dear Leadership Team members and meeting attendees:

Please see the notes from our teleconference this past Wednesday, December 16. Please let me know of any additional comments, questions, or suggestions regarding these notes.

Thank you again for all your support of and contributions to ACTIV.

Regards,

David

David Wholley  
Senior Vice-President, Research Partnerships  
Foundation for the National Institutes of Health  
(b) (6)

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*In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.*

**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
**Sent:** 6/2/2020 2:14:31 AM  
**To:** Jim Neaton [ (b) (6) ]; Jens Lundgren [ (b) (6) ]; Eric Hughes [ (b) (6) ]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Karen Lynn Price [ (b) (6) ]; LaVange, Lisa M [ (b) (6) ]; Sandeep Menon [ (b) (6) ]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Miller, Marissa A (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afea8bcd1c054bcd9250da63e1dbe947-millerma2]; Rachel Harrigan [ (b) (6) ]; William Erhardt [ (b) (6) ]; Gelijns, Annetine [ (b) (6) ]; Moskowitz, Alan [ (b) (6) ]; Ab Babiker [ (b) (6) ]; Cavan, Reilly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=995fe0f1a53c443a832f96f003f0f2c5-cavanr bios]; Phillips, Andrew [ (b) (6) ]; [ (b) (6) ]; Birgit Grund [ (b) (6) ]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f2b26b051964d9da6868e53c9cc6c49-jim.ccbr.um]; Joe Koopmeiners [ (b) (6) ]; David Vock [ (b) (6) ]; Thomas Murray [ (b) (6) ]; Max Parmar [ (b) (6) ]; Mark Polizzotto [ (b) (6) ]; Ginny Kan [ (b) (6) ]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Baker, Jason [ (b) (6) ]; Roger Paredes [ (b) (6) ]; [ (b) (6) ]; [ (b) (6) ]; [ (b) (6) ]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]  
**CC:** Demarcus [ (b) (6) ]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [ (b) (6) ]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Chen, Helen Q. [ (b) (6) ]  
**Subject:** ACTIV-3 Writing Team Meeting  
**Location:** <https://nih.zoom.us/> [ (b) (6) ]  
**Start:** 6/4/2020 4:00:00 PM  
**End:** 6/4/2020 5:00:00 PM  
**Show Time As:** Tentative  
  
**Required Attendees:** Jim Neaton; Jens Lundgren; Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Kozak, Marina (OS/ASPR/BARDA); Patterson, Amy (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Reineck, Lora (NIH/NHLBI) [E]; Judy Currier; Karen Lynn Price; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Miller, Marissa A (NIH/NHLBI) [E]; Rachel Harrigan; William Erhardt; [ (b) (6) ]; Gelijns, Annetine; Moskowitz,

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Alan; Ab Babiker; Cavan, Reilly; Phillips, Andrew (b) (6) Birgit Grund; Neaton, Jim; Joe  
Koopmeiners; David Vock; Thomas Murray; Max Parmar, Mark Polizzotto, Ginny Kan; Lane, Cliff (NIH/NIAID) [E];  
Baker, Jason; Roger Paredes; (b) (6) (b) (6) (b) (6)  
(b) (6) (b) (6) Rosenberg, Yves (NIH/NHLBI) [E]  
**Optional Attendees:** Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Parker, Ashley (NIH/OD) [E]; Chen, Helen Q.

Dear ACTIV-2 and ACTIV-3 Teams,

The ACTIV-3 Writing Team has asked me to move our joint meeting to next week and allow them to use this for just an ACTIV-3 Writing Team meeting, as they think they will need it to work through a few protocol specific issues before they meet with the Steering Committee on Friday.

Thank you all for your understanding. ACTIV-2 folks will see this disappear and ACTIV-3 will remain.

Thanks,

Stacey

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**From:** "Rosenberg, Yves (NIH/NHLBI) [E]" <(b) (6)>  
**Date:** Tuesday, June 16, 2020 at 10:13 AM  
**To:** "Adam, Stacey (FNIH) [T]" <(b) (6)> James Neaton <(b) (6)> Jens Lundgren  
 <(b) (6)> "Read, Sarah (NIH/NIAID) [E]" <(b) (6)> Eric Hughes  
 <(b) (6)> "Srinivasan, Badhri"  
 <(b) (6)> "Goff, David (NIH/NHLBI) [E]" <(b) (6)> "Nayak, Seema  
 (NIH/NIAID) [E]" <(b) (6)> Victoria Davey <(b) (6)> "Kozak, Marina  
 (OS/ASPR/BARDA)" <(b) (6)> "Tierney,  
 John (NIH/NIAID) [E]" <(b) (6)> "Aggarwal, Neil (NIH/NHLBI) [E]" <(b) (6)>  
 "Patterson, Amy (NIH/NHLBI) [E]" <(b) (6)> "Miller, Marissa A (NIH/NHLBI) [E]"  
 <(b) (6)> Rachel Harrigan <(b) (6)> William Erhardt  
 <(b) (6)> "Reineck, Lora (NIH/NHLBI) [E]" <(b) (6)> "Mark Polizzotto  
 <(b) (6)> "Gelijns, Annetine" <(b) (6)> "Baker, Jason"  
 <(b) (6)> Virginia Kan <(b) (6)> 5) "Baker, Jason"  
 <Jason. (b) (6)> Roger Paredes <(b) (6)> Taylor Thompson  
 <(b) (6)> Ab Babiker <(b) (6)>  
**Cc:** "Chen, Helen Q." <(b) (6)> "Wachtel, Jonathan" <(b) (6)> Karen  
 Tountas <(b) (6)> "Desrosiers, Elizabeth A." <(b) (6)> "Kurilla,  
 Michael (NIH/NCATS) [E]" <(b) (6)> "Kenny, Dermot" <(b) (6)>  
 "Parker, Ashley (NIH/OD) [E]" <(b) (6)> Sarah Pett <(b) (6)>  
 "Barrett, Kevin (NIH/NIAID) [E]" <(b) (6)>  
 "Denning, Eileen" <(b) (6)> Eileen Denning <(b) (6)>  
**Subject:** RE: ACTIV-3 Operations Team Meeting

Should we add this to the discussion? Should SOC arm and sample size be modified?

<https://www.recoverytrial.net/news/low-cost-dexamethasone-reduces-death-by-up-to-one-third-in-hospitalised-patients-with-severe-respiratory-complications-of-covid-19>

-----Original Appointment-----

**From:** Adam, Stacey (FNIH) [T] <(b) (6)>  
**Sent:** Monday, June 15, 2020 9:28 PM  
**To:** Jim Neaton; Jens Lundgren; Read, Sarah (NIH/NIAID) [E]; Eric Hughes; Higgs, Elizabeth (NIH/NIAID) [E]; Srinivasan, Badhri; Goff, David (NIH/NHLBI) [E]; Nayak, Seema (NIH/NIAID) [E]; Victoria Davey; Kozak, Marina (OS/ASPR/BARDA); McNay, Laura (NIH/NIAID) [E]; Tierney, John (NIH/NIAID) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Patterson, Amy (NIH/NHLBI) [E]; Miller, Marissa A (NIH/NHLBI) [E]; Rachel Harrigan; William Erhardt; Reineck, Lora (NIH/NHLBI) [E]; Gelijns, Annetine; Mark Polizzotto; Ginny Kan; Baker, Jason; Roger Paredes; Thompson, Taylor, M.D.; Babiker, Ab  
**Cc:** Chen, Helen Q.; Wachtel, Jonathan; Tountas, Karen (FNIH) [T]; Desrosiers, Elizabeth A.; Kurilla, Michael (NIH/NCATS) [E]; Kenny, Dermot; Parker, Ashley (NIH/OD) [E]; Pett, Sarah, Grace, Beth (NIH/NIAID) [C]; Barrett, Kevin (NIH/NIAID) [E]; Denning, Eileen; Eileen Denning  
**Subject:** ACTIV-3 Operations Team Meeting  
**When:** Tuesday, June 16, 2020 12:00 PM-1:00 PM (UTC-05:00) Eastern Time (US & Canada).  
**Where:** <https://fnih.zoom.us>, <(b) (6)>

Dear ACTIV-3 Operations Team,

Please find attached the agenda for tomorrow's meeting. If you have any additions or amendments, please let me know.

Jens or others, if you have slides that you would like me to pre-distribute, send them to me and I will get them out.

Thanks,  
Stacey

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**From:** Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]  
**Sent:** 12/18/2020 8:37:37 PM  
**To:** Harris, Kathryn (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79d72a4a3dcb43e785c83411756cd9e7-HarrisKath]; Tucker, Jessica (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2baf4ae78d90412dbefbfb5e52c31a4-tuckerjm]; O'Reilly, Marina (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54d6c68e99e94ea6bc7872cfbf0d0176-oreillym]  
**Subject:** RE: ACTIV slides from today on escape mutations

I assume a BARDA-funded project would involve funding FNIH to organize the database (including what data exists with the companies already), and maybe FNIH coordinating in vitro assays and small animal testing with new viral strains. I'm not sure who would pay the various labs running the assays and small animal work.

**From:** Harris, Kathryn (NIH/OD) [C] <(b) (6)>  
**Sent:** Friday, December 18, 2020 3:35 PM  
**To:** Tucker, Jessica (NIH/OD) [E] <(b) (6)>; O'Reilly, Marina (NIH/OD) [E] <(b) (6)>  
**Cc:** Gadbois, Ellen (NIH/OD) [E] <(b) (6)>  
**Subject:** RE: ACTIV slides from today on escape mutations

Well BARDA making grantees follow GLs (based on the vaccine stuff they had come to us)

**From:** Tucker, Jessica (NIH/OD) [E] <(b) (6)>  
**Sent:** Friday, December 18, 2020 3:32 PM  
**To:** O'Reilly, Marina (NIH/OD) [E] <(b) (6)>; Harris, Kathryn (NIH/OD) [C] <(b) (6)>  
**Cc:** Gadbois, Ellen (NIH/OD) [E] <(b) (6)>  
**Subject:** FW: ACTIV slides from today on escape mutations

More from Ellen on this.

**From:** Gadbois, Ellen (NIH/OD) [E] <(b) (6)>  
**Sent:** Friday, December 18, 2020 12:11 PM  
**To:** Tucker, Jessica (NIH/OD) [E] <(b) (6)>  
**Subject:** RE: ACTIV slides from today on escape mutations

And more from the FNIH/Deloitte call—Moncef Slaoui is going to ask BARDA for the funds for this project. FNIH is prepping a budget.

**From:** Gadbois, Ellen (NIH/OD) [E]  
**Sent:** Friday, December 18, 2020 10:41 AM  
**To:** Tucker, Jessica (NIH/OD) [E] <(b) (6)>  
**Subject:** RE: ACTIV slides from today on escape mutations

More today on the ACTIV preclinical WG call: FYI this whole effort also includes escape mutants from the vaccines, not just the therapeutics. And I think the member from Roche said something like there are already mutations known to affect efficacy of cocktails (presumably of antibodies), but I am not sure I heard that right. At any rate, I keep hearing the FDA is requiring companies to generate this information.

**From:** Tucker, Jessica (NIH/OD) [E] <(b) (6)>  
**Sent:** Wednesday, December 16, 2020 4:17 PM

Thank you!

See slides 6-10. Note that slide 8 includes “selection screens.” There was general enthusiasm on the call today for the general effort and FC asked industry members what they could do to help. Skip Virgin from VIR said that there are certain experiments that FDA is also asking sponsors to conduct and so centralizing assays and information was important. There was then discussion of a platform that FDA/BARDA/OWS has apparently already built that takes sequence data, makes pseudotype viruses, and run them against a panel of antibodies. (I had to look up pseudotyping—it sounds like it is making a replication incompetent virus.) Not much more detail.

GADB0000000216-2517735

**Cc:** Anderson, James (NIH/OD) [E] < (b) (6) >; Austin, Christopher (NIH/NCATS) [E]  
(b) (6) >; Burklow, John (NIH/OD) [E] (b) (6) >; Carluccio, Dana  
(b) (6) >; Castillejos, Carlos (b) (6) >; FNIH Central Account  
(b) (6) >; Hallett, Adrienne (NIH/OD) [E] (b) (6) >; Lane, Cliff (NIH/NIAID) [E]  
(b) (6) >; Myles, Renate (NIH/OD) [E] (b) (6) >; Parker, Ashley (NIH/OD) [E]  
< (b) (6) >; Tabak, Lawrence (NIH/OD) [E] (b) (6) >; Wolinetz, Carrie (NIH/OD) [E]  
(b) (6) >; Meltzer, Abbey (FNIH) [T] (b) (6)

**Subject:** RE: ACTIV Leadership Team Meeting, Tomorrow, December 16, 2020 -- CORRECTION

Dear ACTIV Leadership Team and meeting attendees:

Please see corrected version of materials. Sorry for the confusion.

Regards,

David

David Wholley  
Senior Vice-President, Research Partnerships  
Foundation for the National Institutes of Health  
(b) (6)

[fnni.org](http://fnni.org)  
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

*In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.*

**From:** Melencio, Cheryl (FNIH) [T] < (b) (6) > **On Behalf Of** Wholley, David (FNIH) [T]  
**Sent:** Tuesday, December 15, 2020 5:08 PM  
**To:** Austin, Christopher (NIH/NCATS) [E] < (b) (6) >; Bancel, Stephane  
(b) (6) >; Carter, Kara (b) (6) >; Cavaleri, Marco  
(b) (6) >; Cihlar, Tomas (b) (6) >; Collins, Francis (NIH/OD) [E]  
(b) (6) >; Corey, Larry (b) (6) >; Culp, Michelle (NIH/OD) [E] < (b) (6) >  
Victoria Davey < (b) (6) >; Disbrow, Gary (OS/ASPR/BARDA) (b) (6) >; Dolsten, Mikael  
(b) (6) >; Erbeling, Emily (NIH/NIAID) [E] (b) (6) >; Erck, Stan  
(b) (6) >; Fauci, Anthony (NIH/NIAID) [E] < (b) (6) >; Freire, Maria (FNIH) [T]  
(b) (6) >; Gadbois, Ellen (NIH/OD) [E] < (b) (6) >; Gibbons, Gary (NIH/NHLBI) [E]  
(b) (6) >; Hudson, Thomas < (b) (6) >; James, Stephanie (FNIH) [T]  
(b) (6) >; Johnson, Robert (OS/ASPR/BARDA) (b) (6) >; Kramer, Lynn  
< (b) (6) >; Lane, Cliff (NIH/NIAID) [E] (b) (6) >; Lepore, John < (b) (6) >  
Marks, Peter (FDA/CBER) < (b) (6) >; Marston, Hilary (NIH/NIAID) [E] < (b) (6) >; >;  
Mascola, John (NIH/VRC) [E] < (b) (6) >; Meeker, David (b) (6) >; Menetski, Joseph  
(FNIH) [T] < (b) (6) >; Messonnier, Nancy (CDC/DDID/NCIRD/OD) < (b) (6) >; Pandya, Hitesh  
(b) (6) >; Pangalos, Mene (b) (6) >; Pao, William  
(b) (6) >; Parker, Ashley (NIH/OD) [E] < (b) (6) >; Paul, Steve (b) (6) >  
Perlmutter, Roger (b) (6) >; Plenge, Robert < (b) (6) >; Plump, Andy  
(b) (6) >; Rachel Ramoni (b) (6) >; Reed, John < (b) (6) >; >; Reese,  
David (b) (6) >; Rouse, Doris < (b) (6) >; Santos, Michael (FNIH) [T] (b) (6) >; >;  
Skovronsky, Daniel (b) (6) >; Stein, Peter (FDA/CDER) (b) (6) >; Stoffels, Paul  
(b) (6) >; >; Tabak, Lawrence (NIH/OD) [E] < (b) (6) >; >; Talley, Michael

(b) (6) ; Tsai, John < (b) (6) Vessey, Rupert < (b) (6) . Virgin, Skip  
 (b) (6) >> Wholley, David (FNIH) [T] < (b) (6) > Woodcock, Janet (FDA/CDER)  
 (b) (6) > Young, John < (b) (6) > Colvis, Christine (NIH/NCATS) [E]  
 < (b) (6) > Desrosiers, Betsy (b) (6) Eric Hughes  
 (b) (6) > Jansen, Kathrin (b) (6) Kurilla, Michael (NIH/NCATS) [E]  
 (b) (6) Lowry, Douglas (NCI) < (b) (6) Read, Sarah (NIH/NIAID) [E] (b) (6)  
 Young, John (b) (6) Adam, Stacey (FNIH) [T] (b) (6) Margaret Anderson  
 < (b) (6) Appell, Evan (b) (6) Chen, Helen Q. (b) (6) >;  
 Connelly, Sarah (b) (6) > Gonzalez, Nina (b) (6) ; Hawk, Harrison  
 (b) (6) > Mendelson, Jesse (b) (6) ; Menetski, Joseph (FNIH) [T]  
 (b) (6) > Nasr, Hana < (b) (6) > Santos, Michael (FNIH) [T] (b) (6) > Sorosa,  
 Alex David (b) (6) ; Stratton, Benjamin (b) (6) > btolman < (b) (6) >;  
 Tountas, Karen (FNIH) [T] (b) (6) ; Wachtel, Jonathan < (b) (6) Wholley, David (FNIH) [T]  
 (b) (6)  
**Cc:** Anderson, James (NIH/OD) [E] < (b) (6) Austin, Christopher (NIH/NCATS) [E]  
 (b) (6) Burklow, John (NIH/OD) [E] (b) (6) Carluccio, Dana  
 (b) (6) > Castillejos, Carlos (b) (6) FNIH Central Account  
 (b) (6) > Hallett, Adrienne (NIH/OD) [E] (b) (6) (b) (6) Lane, Cliff (NIH/NIAID) [E]  
 (b) (6) > My es, Renate (NIH/OD) [E] < (b) (6) > Parker, Ashley (NIH/OD) [E]  
 (b) (6) ; Tabak, Lawrence (NIH/OD) [E] < (b) (6) ; Wolinetz, Carrie (NIH/OD) [E]  
 (b) (6) > Meltzer, Abbey (FNIH) [T] < (b) (6)

**Subject:** ACTIV Leadership Team Meeting, Tomorrow, December 16, 2020

Dear ACTIV Leadership Team and meeting attendees:

Attached please find the slides for our meeting **tomorrow, Wednesday, December 16, 10:00 – 11:30 a.m. Eastern U.S. Time.** The minutes from the November 19 Leadership Team call are attached to this note.

The logistics for the Zoom call, which were previously sent to you in the Outlook calendar invitation, are as follows:

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley  
Senior Vice-President, Research Partnerships  
Foundation for the National Institutes of Health

(b) (6)

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*In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.*

**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
**Sent:** 2/27/2021 2:14:36 AM  
**To:** Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [ (b) (6) Gottesdiener, Keith [ke (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [ (b) (6) LaVange, Lisa [ (b) (6) Levy, Elliot [ (b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras], Patel, Naimish [na (b) (6) Peppercorn, Amanda [ (b) (6) Poole, Mike [ (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia Colli]; Amanda Peppercorn [ (b) (6) Garner, Carl (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dc8c847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [ (b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative

Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Philips, L Revell CIV DTRA RD (USA) [ (b) (6) Petrovick, Martha - 0449 - MITLL [ (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Larry Tsai [ (b) (6) Wung, Peter K [ (b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Jansen, Kathrin [ (b) (6) Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [john. (b) (6) Biggs, Mary [ (b) (6) Butcher, Tina [ (b) (6) Demarcus [ (b) (6) Macone, Erin [ (b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [ (b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Dana Carluccio [ (b) (6) Rose Li Central Account [ (b) (6) Lucas Smalldon [ (b) (6) Mollica, Linda /US [ (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Hoots, W Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [ (b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) [ (b) (6) Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact\_f12]; Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; Lerner, Andrea (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53254f4fb04e4bcbabe37940b4b41887-fennellyam]; Embry, A an (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]

**Subject:** Summary of the ACTIV Therapeutics-Clinical Working Group

**Attachments:** 2021-02-25\_TX-Clinical\_WG\_Meeting\_Summary.pdf

Dear ACTIV TX-Clinical WG,

Please find attached the summary of the meeting yesterday. I want to once again thank John for presenting the ACTT 3 results. ***We would ask that you all please keep the summary of these results confidential to this group.***

Thanks,  
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

Direct: (b) (6) , Mobile: (b) (6)

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To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (N.H/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) Baric, Ra ph  
 (b) (6) (b) (6) (b) (6) (b) (6)  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];  
 (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] (b) (6) Colvis, Christine  
 (NIH/NCATS) [E] (b) (6) Hewitt, Judith (NIH/NIAID) [E] (b) (6) Deming, Damon  
 (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];  
 (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras],  
 (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas  
 [ (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar  
 [ (b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [ (b) (6)  
 Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc  
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI)  
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; Isis. (b) (6)  
 (b) (6) (b) (6) (b) (6)  
 CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Austin, Christopher  
 (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melenc o, Cheryl (FNIH) [T]  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine  
 (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy  
 [ (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin  
 [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI)  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID)  
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T]  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T]  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T]  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T]  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria  
 [ (b) (6) Kim, Elizabeth [ (b) (6) btolman [ (b) (6) Wachtel,  
 Jonathan (b) (6) Prabhavathi Fernandes [ (b) (6) Rose Li  
 [ (b) (6) Dana Carluccio [ (b) (6) Lagos, Enrique (NIH/NCATS)  
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha  
 (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina  
 [ (b) (6) Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [ (b) (6) Dave Frankowski [ (b) (6) antoinette\_baric [ (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowy]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon oh]; Stratton, Benjamin [ (b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison [ (b) (6) Mason, Stephen [Stephen. (b) (6) Connelly, Sarah [ (b) (6) (b) (6) Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; K C Kent Lloyd [ (b) (6) (b) (6) Embry, Alan (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]; (b) (6) Lerner, Andrea (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53254f4fb04e4bcbabe37940b4b41887-fennellyam]; Diamond, Michael [ (b) (6)

**Start:** 2/17/2021 3:00:00 PM

**End:** 2/17/2021 4:00:00 PM

**Recurrence:** (none)



**From:** Brodd, Lauren (N H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BA665DEA08E54171B3D6890C2518DDB9-LEPONELM]  
**Sent:** 11/23/2020 5:28:58 PM  
**To:** Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]  
**Subject:** RE: Notes from Thursday's ACTIV Leadership Team Meeting

Thanks!

**From:** Parker, Ashley (NIH/OD) [E] <(b) (6)>  
**Sent:** Monday, November 23, 2020 11:34 AM  
**To:** Brodd, Lauren (NIH/OD) [E] <(b) (6)>  
**Subject:** FW: Notes from Thursday's ACTIV Leadership Team Meeting

**From:** Melencio, Cheryl (FNIH) [T] <(b) (6)> , On Behalf Of Wholley, David (FNIH) [T]  
**Sent:** Monday, November 23, 2020 11:18 AM  
**To:** Austin, Christopher (NIH/NCATS) [E] <(b) (6)> ; Bancel, Stephane  
(b) (6) ; Carter, Kara <(b) (6)> ; Cavaleri, Marco  
<(b) (6)> ; Cihlar, Tomas (b) (6) ; Collins, Francis (NIH/OD) [E]  
(b) (6) ; Corey, Larry (b) (6) ; Culp, Michelle (NIH/OD) [E] (b) (6)  
Victoria Davey <(b) (6)> Disbrow, Gary (OS/ASPR/BARDA) (b) (6) ; Dolsten, Mikael  
(b) (6) Erbeling, Emily (NIH/NIAID) [E] (b) (6) ; Erck, Stan  
(b) (6) Fauci, Anthony (NIH/NIAID) [E] (b) (6) Freire, Maria (FNIH) [T]  
(b) (6) Gadbois, Ellen (NIH/OD) [E] (b) (6) Gibbons, Gary (NIH/NHLBI) [E]  
(b) (6) ; Hudson, Thomas (b) (6) ; James, Stephanie (FNIH) [T]  
(b) (6) Johnson, Robert (OS/ASPR/BARDA) (b) (6) ; Kramer, Lynn  
(b) (6) ; Lane, Cliff (NIH/NIAID) [E] (b) (6) ; Lepore, John <(b) (6)>  
Marks, Peter (FDA/CBER) (b) (6) ; Marston, Hilary (NIH/NIAID) [E] (b) (6)  
Mascola, John (NIH/VRC) [E] <(b) (6)> Meeker, David (b) (6) ; Menetski, Joseph  
(FNIH) [T] <(b) (6)> Messonnier, Nancy (CDC/DDID/NCIRD/OD) (b) (6) ; Pandya, Hitesh  
(b) (6) ; Pangalos, Mene (b) (6) Pao, William  
(b) (6) Parker, Ashley (NIH/OD) [E] (b) (6) ; Paul, Steve <(b) (6)>  
Perlmutter, Roger <(b) (6)> Plenge, Robert (b) (6) Plump, Andy  
<(b) (6)> Rachel Ramoni (b) (6) Reed, John (b) (6) ; Reese,  
David <(b) (6)> Rouse, Doris <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)>  
Skovronsky, Daniel (b) (6) Stein, Peter (FDA/CDER) <(b) (6)> Stoffels, Paul  
(b) (6) ; Tabak, Lawrence (NIH/OD) [E] (b) (6) Talley, Michael  
(b) (6) Tsai, John (b) (6) Vessey, Rupert (b) (6) ; Virgin, Skip  
(b) (6) ; Wholley, David (FNIH) [T] (b) (6) Woodcock, Janet (FDA/CDER)  
(b) (6) Young, John (b) (6) ; Colvis, Christine (NIH/NCATS) [E]  
(b) (6) Desrosiers, Betsy (b) (6) Eric Hughes  
(b) (6) ; Jansen, Kathrin <(b) (6)> Kurilla, Michael (NIH/NCATS) [E]  
(b) (6) Lowy, Douglas (NCI) (b) (6) Read, Sarah (NIH/NIAID) [E] (b) (6)  
Young, John (b) (6)  
**Cc:** Anderson, James (NIH/OD) [E] (b) (6) ; Burklow, John (NIH/OD) [E] (b) (6) ;  
Carluccio, Dana <(b) (6)> Castillejos, Carlos <(b) (6)> FNIH Central Account  
(b) (6) ; Gadbois, Ellen (NIH/OD) [E] (b) (6) Hallett, Adrienne (NIH/OD) [E]  
(b) (6) ; Lane, Cliff (NIH/NIAID) [E] (b) (6) ; Parker, Ashley (NIH/OD) [E]  
(b) (6) Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Wolinetz, Carrie (NIH/OD) [E]

< (b) (6) Gorman, Greta (FNIH) [T] (b) (6) >; Meltzer, Abbey (FNIH) [T]  
 < (b) (6) >; Myles, Renate (NIH/OD) [E] (b) (6) >; Wolinetz, Carrie (NIH/OD) [E]  
 (b) (6) >; Adam, Stacey (FNIH) [T] (b) (6) ; Margaret Anderson  
 < (b) (6) >; Appell, Evan ( ; Chen, Helen Q. (b) (6)  
 Connelly, Sarah (b) (6) Gonzalez, Nina (b) (6) >; Hawk, Harrison  
 (b) (6) >; Mendelson, Jesse (b) (6) . Menetski, Joseph (FNIH) [T]  
 (Santos, Michael (FNIH) [T] < (b) (6) , asorosa (b) (6) ; Stratton,  
 Benjamin (b) (6) >; btolman < (b) (6) . Tountas, Karen (FNIH) [T]  
 (b) (6) ; Wachtel, Jonathan (b) (6) Wholley, David (FNIH) [T] (b) (6)

**Subject:** Notes from Thursday's ACTIV Leadership Team Meeting

Dear Leadership Team members and meeting attendees:

Please see the notes from our teleconference this past Thursday, November 19. Please let me know any additional comments, questions, or suggestions regarding these notes or the action items.

Thank you again for all your support of and contributions to ACTIV.

Regards,

David

David Wholley  
 Senior Vice-President, Research Partnerships  
 Foundation for the National Institutes of Health

(b) (6)

[fnih.org](http://fnih.org)

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

*In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.*

**From:** Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]  
**Sent:** 1/13/2021 7:04:15 PM  
**To:** Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]  
**Subject:** FW: ACTIV Joint Executive Committee & Leadership Team Meeting: tomorrow, January 14, 2021  
**Attachments:** 01.14 ACTIV EC and Leadersh p Team Meeting 20210113 vF2.pdf; 01.14 ACTIV EC and Leadership Team Meeting\_APPENDIX 20210113 vF.pdf; 2020-12-16\_ACTIV\_Leadership\_Team\_\_and\_Executive\_Committee\_Meeting\_Summary\_vF.docx

FYI

**From:** Melencio, Cheryl (FNIH) [T] < (b) (6) > **On Behalf Of** Wholley, David (FNIH) [T]  
**Sent:** Wednesday, January 13, 2021 1:38 PM  
**To:** Austin, Christopher (NIH/NCATS) [E] < (b) (6) > Bancel, Stephane  
< (b) (6) > Carter, Kara < (b) (6) > Cavaleri, Marco  
< (b) (6) > Cihlar, Tomas < (b) (6) > Collins, Francis (NIH/OD) [E]  
< (b) (6) > Corey, Larry < (b) (6) > Culp, Michelle (NIH/OD) [E] < (b) (6) >  
Victoria Davey < (b) (6) > Disbrow, Gary (OS/ASPR/BARDA) < (b) (6) > Dolsten, Mikael  
< (b) (6) > Erbeling, Emily (NIH/NIAID) [E] < (b) (6) > Erck, Stan  
< (b) (6) > Fauci, Anthony (NIH/NIAID) [E] < (b) (6) > Freire, Maria (FNIH) [T]  
< (b) (6) > Gadbois, Ellen (NIH/OD) [E] < (b) (6) > Gibbons, Gary (NIH/NHLBI) [E]  
< (b) (6) > Hudson, Thomas < (b) (6) > James, Stephanie (FNIH) [T]  
< (b) (6) > Johnson, Robert (OS/ASPR/BARDA) < (b) (6) > Kramer, Lynn  
< (b) (6) > Lane, Cliff (NIH/NIAID) [E] < (b) (6) > Lepore, John < (b) (6) >  
Marks, Peter (FDA/CBER) < (b) (6) > Marston, Hilary (NIH/NIAID) [E] < (b) (6) >  
Mascola, John (NIH/VRC) [E] < (b) (6) > Meeker, David < (b) (6) > Menetski, Joseph  
(FNIH) [T] < (b) (6) > Messonnier, Nancy (CDC/DDID/NCIRD/OD) < (b) (6) > Pandya, Hitesh  
< (b) (6) > Pangalos, Mene < (b) (6) > Pao, William  
< (b) (6) > Parker, Ashley (NIH/OD) [E] < (b) (6) > Paul, Steve < (b) (6) >  
Perlmutter, Roger < (b) (6) > Plenge, Robert < (b) (6) > Plump, Andy  
< (b) (6) > Rachel Ramoni < (b) (6) > Reed, John < (b) (6) > Reese,  
David < (b) (6) > Rouse, Doris < (b) (6) > Santos, Michael (FNIH) [T] < (b) (6) >  
Skovronsky, Daniel < (b) (6) > Stein, Peter (FDA/CDER) < (b) (6) > Stoffels, Paul  
< (b) (6) > Tabak, Lawrence (NIH/OD) [E] < (b) (6) > Talley, Michael  
< (b) (6) > Tsai, John < (b) (6) > Vessey, Rupert < (b) (6) > Virgin, Skip  
< (b) (6) > Wholley, David (FNIH) [T] < (b) (6) > Woodcock, Janet (FDA/CDER)  
< (b) (6) > Young, John < (b) (6) > Colvis, Christine (NIH/NCATS) [E]  
< (b) (6) > Desrosiers, Betsy < (b) (6) > Eric Hughes  
< (b) (6) > Jansen, Kathrin < (b) (6) > Kurilla, Michael (NIH/NCATS) [E]  
< (b) (6) > Lowy, Douglas (NCI) < (b) (6) > Read, Sarah (NIH/NIAID) [E] < (b) (6) >  
Young, John < (b) (6) > Adam, Stacey (FNIH) [T] < (b) (6) > Margaret Anderson  
< (b) (6) > Appell, Evan < (b) (6) > Chen, Helen < (b) (6) >  
Connelly, Sarah < (b) (6) > Gonzalez, Nina < (b) (6) > Hawk, Harrison  
< (b) (6) > Mendelson, Jesse < (b) (6) > Menetski, Joseph (FNIH) [T]  
< (b) (6) > Nasr, Hana < (b) (6) > Santos, Michael (FNIH) [T] < (b) (6) > Sorosa,  
Alex < (b) (6) > Stratton, Benjamin < (b) (6) > btolman < (b) (6) >  
Wachtel, Jonathan < (b) (6) > Wholley, David (FNIH) [T] < (b) (6) > Anderson, James  
(NIH/OD) [E] < (b) (6) > Burklow, John (NIH/OD) [E] < (b) (6) > Carluccio, Dana  
< (b) (6) > Castillejos, Carlos < (b) (6) > Culp, Michelle (NIH/OD) [E]  
< (b) (6) > FNIH Central Account < (b) (6) > Gadbois, Ellen (NIH/OD) [E]  
< (b) (6) > Hallett, Adrienne (NIH/OD) [E] < (b) (6) > Lumsden, Joanne (NIH/NCATS) [C]



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Meeting ID: (b) (6)

Passcode: (b) (6)

Find your local number: <https://fnih.zoom.us> (b) (6)

Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley  
Senior Vice-President, Research Partnerships  
Foundation for the National Institutes of Health

(b) (6)

[fnih.org](https://fnih.org)  
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

*In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.*



**From:** Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]  
**Sent:** 7/15/2020 5:38:24 PM  
**To:** Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr];

(b) (6) Lowy, Douglas (NIH/NCI) [E] [ (b) (6) (b) (6)  
Arvin, Ann (b) (6) ; Beth Bell ( (b) (6) [ (b) (6)  
susan. (b) (6) Cavaleri Marco [Marco.Cava (b) (6) (b) (6)  
(b) (6) (b) (6) Greg Glenn [ (b) (6)  
(b) (6) Haynes, Barton [ (b) (6) (b) (6) (b) (6)  
Marks, Peter (FDA/CBER) [ (b) (6) Mascola, John (NIH/VRC) [E] [ (b) (6)  
Messonnier, Nancy (CDC/DDID/NCIRD/OD) [ (b) (6) Nelson Michael [ (b) (6)  
Offit, Paul [ (b) (6) Seals, Jonathan (OS/ASPR/BARDA) [Jonathan. (b) (6)  
(b) (6) (b) (6) Tal Zaks [ (b) (6) Collins, Francis  
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf], (b) (6)  
**CC:** Tolman, Brett [ (b) (6) (b) (6) Hopps, Markay [ (b) (6)  
Kozlowski, Mary (NIH/NCI) [C] [ (b) (6) Johnson, Maureen (NIH/NCI) [E]  
[ (b) (6) (b) (6) Jeneffer Haynes [ (b) (6)  
(b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E]  
[ (b) (6) .gov]; (b) (6) Isabel Ramsey [ (b) (6) Parker,  
Ashley (NIH/OD) [E] [ (b) (6) Marston, Hilary (NIH/NIAID) [E] [ (b) (6) ]; Qashu,  
Felicia (NIH/OD) [E] (b) (6) ; Culp, Michelle (NIH/OD) [E] [ (b) (6) Gadbois, Ellen  
(NIH/OD) [E] [ (b) (6) Wholley, David (FNIH) [T] [dwhol (b) (6) Melencio, Cheryl (FNIH) [T]  
[ (b) (6) Menetski, Joseph (FNIH) [T] [ (b) (6) Adam, Stacey (FNIH) [T] [ (b) (6)  
Tountas Karen (FNIH) [T] (b) (6) ; James, Stephanie (FNIH) [T] [ (b) (6) Colvis, Christine  
(NIH/NCATS) [E] (b) (6) Desrosiers, Betsy [el (b) (6) Hughes, Eric  
[ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [ (b) (6) Read, Sarah (NIH/NIAID) [E]  
[ (b) (6) Paul Gillard [ (b) (6) François P Roman [ (b) (6)  
Hamilton, Holli (OS/ASPR/BARDA) (b) (6) Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR  
(USA) [kayvon modja (b) (6) Kathleen Neuzil (b) (6) Schrag, Stephanie  
(CDC/DDID/NCIRD/DBD) [ (b) (6) Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) [ (b) (6)  
Thornburg, Natalie (CDC/DDID/NCIRD/DVD) [ (b) (6) Gonzalez, Nina [ (b) (6) 'Wachtel,  
Jonathan' [ (b) (6) Stratton, Benjamin [ (b) (6) (b) (6)  
(b) (6) Bethany Stokes [ (b) (6) Kathleen Callahan  
[ (b) (6) Arvin, Ann [ (b) (6) Wood, Gretchen (NIH/OD) [E]  
[ (b) (6) Young, John [ (b) (6) Anderson, Margaret  
[ (b) (6) Filip Dubovsky [ (b) (6)

**Subject:** ACTIV Vaccines Working Group meeting

**Location:** Webex: <https://nih.webex.com/n> (b) (6)

**Start:** 7/29/2020 2:00:00 PM

**End:** 7/29/2020 3:00:00 PM

**Show Time As:** Busy

**Required Attendees:** (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6) Arvin, Ann; Beth Bell  
(b) (6) (b) (6) Cavaleri Marco; (b) (6)  
(b) (6) (b) (6) ; Greg Glenn; (b) (6) Haynes,  
Barton; (b) (6) Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E];  
Messonnier, Nancy (CDC/DDID/NCIRD/OD); Nelson Michael; Offit, Paul (b) (6) ; Seals, Jonathan  
(OS/ASPR/BARDA); (b) (6) ; Tal Zaks; Collins, Francis (NIH/OD)  
[E]  
**Optional Attendees:** Tolman, Brett; (b) (6) Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen  
(NIH/NCI) [E]; (b) (6) Jeneffer Haynes; (b) (6) (b) (6)

(b) (6) Austin, Sarah (NIH/NIAID) [E]; (b) (6) Isabel Ramsey; Parker,  
Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E];  
Gadbois, Ellen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T];  
Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E];  
Desrosiers, Betsy, Hughes, Eric; Kunilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul  
Gillard; François P Roman; Hamilton, Holly (OS/ASPR/BARDA); Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR  
(USA); Kathleen Neuzil; Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R (CDC/DDID/NCIRD/DBD);  
Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin; Anderson,  
Margaret; (b) (6) (b) (6) Bethany Stokes; Kathleen Callahan;  
Ann Arvin; Wood, Gretchen (NIH/OD) [E]; Filip Dubovsky

### Join Webex meeting

Meeting number (access code): (b) (6) Meeting password: (b) (6)

#### **Join from a video system or application**

Dial (b) (6) @nih.webex.com

You can also dial (b) (6) and enter your meeting number

#### **Tap to join from a mobile device (attendees only)**

(b) (6) Call-in toll number (US/Canada)

#### **Join by phone**

(b) (6) Call-in toll number (US/Canada)

Global call-in numbers

#### **Join using Microsoft Lync or Microsoft Skype for Business**

Dial (b) (6) @lync.webex.com

(b) (6)

If you are a host, [click here to view host information](#). **IMPORTANT NOTICE:** Please note that this Webex service allows a

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**From:** Patel, Naimish /US [ (b) (6)]  
**Sent:** 5/15/2020 2:49:06 AM  
**To:** Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]  
**CC:** Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak], Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]  
**Subject:** Time sensitive: Making your ACTIV Participation Public

Dear Francis,

I would be happy to have my name listed on the website.

Best,  
Naimish

**From:** "Collins, Francis (NIH/OD) [E]" < (b) (6)>  
**Date:** Thursday, May 14, 2020 at 11:03 AM  
**To:** "Collins, Francis (NIH/OD) [E]" < (b) (6)>  
**Cc:** "Myles, Renate (NIH/OD) [E]" < (b) (6)> "Meltzer, Abbey (FNIH) [T]" < (b) (6)> "Wholley, David (FNIH) [T]" < (b) (6)>  
**Subject:** [EXTERNAL] Time sensitive: Making your ACTIV Participation Public

**EXTERNAL :** Real sender is (b) (6)

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.**

Thanks,  
Francis

Francis S. Collins, MD, PhD  
NIH Director

---

**From:** Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]  
**Sent:** 5/15/2020 9:02:26 AM  
**To:** Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]  
**Subject:** FW: Time sensitive: Making your ACTIV Participation Public

**From:** Emmanuel Hanon < > (b) (6)  
**Sent:** Friday, May 15, 2020 2:32 AM  
**To:** Collins, Francis (NIH/OD) [E] < > (b) (6)  
**Subject:** Re: Time sensitive: Making your ACTIV Participation Public

Ok for me  
R  
M

**From:** "Collins, Francis (NIH/OD) [E]" < > (b) (6)  
**Date:** Thursday, 14 May 2020 at 17:00  
**To:** "Collins, Francis (NIH/OD) [E]" < > (b) (6)  
**Cc:** "Myles, Renate (NIH/OD) [E]" < > (b) (6), "Meltzer, Abbey (FNIH) [T]" < > (b) (6), "Wholley, David (FNIH) [T]" < > (b) (6)  
**Subject:** Time sensitive: Making your ACTIV Participation Public

EXTERNAL

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.**

Thanks,  
Francis

Francis S. Collins, MD, PhD  
NIH Director

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is conducted with appropriate confidentiality controls and in accordance with local laws and after appropriate consultation.

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**From:** Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C1B522-MYLESR]  
**Sent:** 3/4/2021 11:04:28 PM  
**To:** Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf], Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak], Thompson, Katherine (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f2c78f864ae4355adb82dc6b9a4d71-thompsonkap]  
**CC:** Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc], Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Gonzalez, Nina [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Appell, Evan [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Wojtowicz, Emma (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45c6610aca6e44a08d497630425e5ecd-wojtowiczem]  
**Subject:** RE: Notes from Wednesday's ACTIV Leadership Team Meeting

Also, should we change Janet Woodcock's organization to FDA? We are also checking with HHS to determine if we change OWS to COVID-19 Vaccines/Therapeutics Operation.

**From:** Myles, Renate (NIH/OD) [E]  
**Sent:** Thursday, March 4, 2021 3:23 PM  
**To:** Collins, Francis (NIH/OD) [E] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Meltzer, Abbey (FNIH) [T] <(b) (6)> Thompson, Katherine (FNIH) [T] <(b) (6)>  
**Cc:** Freire, Maria (FNIH) [T] <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Melencio, Cheryl (FNIH) [T] <(b) (6)> Meltzer, Abbey (FNIH) [T] <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Gonzalez, Nina <(b) (6)> Appell, Evan <(b) (6)> Wojtowicz, Emma (NIH/OD) [E] <(b) (6)>  
**Subject:** RE: Notes from Wednesday's ACTIV Leadership Team Meeting

Hi David:

We list the Executive Committee on the ACTIV page and can replace Andy with Rajev on the [organization chart](#) and the [Executive Committee governance](#) page. We don't actually list the leadership on the ACTIV page.

Cheryl: will you be coordinating as per usual to see if these folks agree to be listed on the page and how they want to be listed?

Thanks,  
Renate



**From:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Sent:** Thursday, March 4, 2021 2:54 PM  
**To:** Wholley, David (FNIH) [T] (b) (6); Myles, Renate (NIH/OD) [E] (b) (6); Meltzer, Abbey (FNIH) [T] (b) (6); Thompson, Katherine (FNIH) [T] (b) (6)  
**Cc:** Freire, Maria (FNIH) [T] (b) (6); Santos, Michael (FNIH) [T] (b) (6); Melencio, Cheryl (FNIH) [T] (b) (6); Meltzer, Abbey (FNIH) [T] <(b) (6)>; Parker, Ashley (NIH/OD) [E] <(b) (6)>; Gonzalez, Nina (b) (6); Appell, Evan (b) (6)  
**Subject:** RE: Notes from Wednesday's ACTIV Leadership Team Meeting

I'm fine with that plan.

FC

**From:** Wholley, David (FNIH) [T] (b) (6)  
**Sent:** Thursday, March 4, 2021 1:08 PM  
**To:** Myles, Renate (NIH/OD) [E] (b) (6); Meltzer, Abbey (FNIH) [T] (b) (6); Thompson, Katherine (FNIH) [T] (b) (6)  
**Cc:** Freire, Maria (FNIH) [T] (b) (6); Santos, Michael (FNIH) [T] (b) (6); Melencio, Cheryl (FNIH) [T] <(b) (6)>; Meltzer, Abbey (FNIH) [T] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6); Parker, Ashley (NIH/OD) [E] (b) (6); Gonzalez, Nina (b) (6); Appell, Evan (b) (6)  
**Subject:** FW: Notes from Wednesday's ACTIV Leadership Team Meeting

Can we please add Gary Dubin to the Vaccine WG rosters on the NIH and FNIH websites, and substitute Rajeev Venkayya for Andy Plump as the rep for Takeda to the ACTIV Leadership Team?

Francis, I am assuming this means Andy is also asking that Rajeev replace him on the Executive Committee. He's got a good background for PPPs—worked for four years on the WH biodefense team (wherefrom he knows Tony Fauci), is Andy's counterpart at Takeda as global head of their vaccines business, directed vaccines delivery at BMGF, and serves on the boards of SEPI and IAVI. I found him engaging and impressive, and am guessing Mike did too.  
Thanks, David

**From:** Burke, Leslie (b) (6) **On Behalf Of** Venkayya, Rajeev  
**Sent:** Thursday, March 4, 2021 12:03 PM  
**To:** Santos, Michael (FNIH) [T] (b) (6)  
**Cc:** Wholley, David (FNIH) [T] <(b) (6)>; Melencio, Cheryl (FNIH) [T] <(b) (6)>; Venkayya, Rajeev <(b) (6)>  
**Subject:** RE: Notes from Wednesday's ACTIV Leadership Team Meeting

Dear Mike,

I'm following up on Rajeev's behalf to let you know he would like to recommend his colleague **Gary Dubin, MD** (b) (6) for the Vaccines WG. Gary is the Head of our Global Medical Office, and leads the Takeda Vaccine Business Medical Affairs and Policy team (b) (6), is his Executive Assistant.

Gary will look forward to connecting!

Please don't hesitate to reach out with any questions.

Many thanks,

## Leslie Burke

EA to Rajeev Venkayya, MD, President, Global Vaccine Business Unit  
Vaccine Business Unit

### Takeda Pharmaceutical Company Limited

Mail to: 40 Landsdowne Street, Cambridge, MA 02139, USA

Office location: 75 Sidney Street, Cambridge, MA 02139, USA

mobile: (

email: (b) (6) | [www.takedavaccines.com](http://www.takedavaccines.com)

**From:** Santos, Michael (FNIH) [T] (b) (6)

**Sent:** Monday, March 1, 2021 12:04 PM

**To:** Venkayya, Rajeev < (b) (6)

**Cc:** Wholley, David (FNIH) [T] (b) (6), Melencio, Cheryl (FNIH) [T] (b) (6) >; Burke, Leslie (b) (6)

**Subject:** RE: Notes from Wednesday's ACTIV Leadership Team Meeting

Be advised that this email came from outside Takeda / お知らせ:社外から送信されたメールです

Hi Rajeev,

It was great meeting and chatting. Your experience and perspectives are a great addition to the group.

As we discussed, attached are notes from the last few Vaccines WG meetings. The meetings are not under NDA, but our principle is that information shared during the meetings should only be used to advanced the shared objective of supporting COVID-19 vaccine development. So please feel free to share with the relevant people in your team, but not publicly.

If anyone is interested in joining the Vaccines Working Group, please let us know and we'll be happy to add them.

Best regards,  
Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

**From:** Venkayya, Rajeev (b) (6) >

**Sent:** Friday, February 19, 2021 11:21 PM

**To:** Santos, Michael (FNIH) [T] (b) (6)

**Cc:** Wholley, David (FNIH) [T] (b) (6), Melencio, Cheryl (FNIH) [T] (b) (6), Burke, Leslie (b) (6)

**Subject:** Re: Notes from Wednesday's ACTIV Leadership Team Meeting

Dear Michael,

Thanks for the kind introduction and background. I know FNIH well and am looking forward to working with you. And yes, I'm sure we have many colleagues in common from BMGF!

An onboarding call would be helpful if it's not too much trouble. I'll ask Leslie to work with you to set that up. I look forward to that, and to meeting the ACTIV group!

Regards,

Rajeev

**From:** Santos, Michael (FNIH) [T] (b) (6)  
**Sent:** Friday, February 19, 2021 4:59:22 PM  
**To:** Venkayya, Rajeev (b) (6)  
**Cc:** Wholley, David (FNIH) [T] (b) (6) >; Melencio, Cheryl (FNIH) [T] (b) (6)  
**Subject:** RE: Notes from Wednesday's ACTIV Leadership Team Meeting

Be advised that this email came from outside Takeda / お知らせ:社外から送信されたメールです

Dear Rajeev,

We heard from Andy Plump and Francis Collins that you are joining ACTIV. We're delighted to have you on the team.

The Foundation for the NIH manages ACTIV; David Wholley leads our work overall, I manage the Vaccines Working Group, and my counterparts manage the other Working Groups. If you are interested, we would be happy to have a call to provide context on ACTIV and the Vaccines Working Group and answer any questions that you have.

On a personal note, I was at BMGF for almost 6 years on the Discovery and HIV teams before I joined FNIH in late 2019. Although we missed overlapping there, I'm sure we know many people in common and I hope that we'll have the opportunity to connect sometime.

Best regards,  
Mike

Michael Santos, PhD  
Associate Vice President, Science | Foundation for the National Institutes of Health

**From:** Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]  
**Sent:** Friday, February 19, 2021 4:07 PM  
**To:** Austin, Christopher (NIH/NCATS) [E] (b) (6) : Bancel, Stephane  
(b) (6) >; Carter, Kara (b) (6) ; Cavaleri, Marco  
Cihlar, Tomas ; Collins, Francis (NIH/OD) [E]  
(b) (6) ; Corey, Larry (b) (6) >; Culp, Michelle (NIH/OD) [E] <(b) (6)>  
Victoria Davey <(b) (6)> Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)> ; Dolsten, Mikael  
(b) (6) >; Embry, Alan (NIH/NIAID) [E] (b) (6) ; Erbelding, Emily (NIH/NIAID) [E]  
, Erck, Stan (b) (6) >; Fauci, Anthony (NIH/NIAID) [E] (b) (6)  
Freire, Maria (FNIH) [T] (b) (6) , Gadbois, Ellen (NIH/OD) [E] (b) (6) ; Gibbons, Gary  
(NIH/NHLBI) [E] (b) (6) >; Hudson, Thomas (b) (6) >; James, Stephanie (FNIH) [T]  
(b) (6) ; Johnson, Robert (OS/ASPR/BARDA) (b) (6) ; Kramer, Lynn  
(b) (6) ; Lane, Cliff (NIH/NIAID) [E] (b) (6) ; Lepore, John <(b) (6)>  
Marks, Peter (FDA/CBER) (b) (6) >; Mascola, John (NIH/VRC) [E] (b) (6) ; Meeker,  
David (b) (6) ; Menetski, Joseph (FNIH) [T] <(b) (6)> ; Messonnier, Nancy  
(CDC/DDID/NCIRD/OD) (b) (6) ; Pandya, Hitesh (b) (6) ; Pangalos, Mene  
(b) (6) ; Pao, William <(b) (6)> ; Parker, Ashley (NIH/OD) [E]

(b) (6) >; Paul, Steve (b) (6) Perlmutter, Roger (b) (6)  
 Plenge, Robert (b) (6) Reed, John (b) (6) ; Reese, David < (b) (6) ;  
 Rouse, Doris < (b) (6) Santos, Michael (FNIH) [T] (b) (6) ; Skovronsky, Daniel  
 (b) (6) Stein, Peter (FDA/CDER) (b) (6) ; Stoffels, Paul  
 (b) (6) Tabak, Lawrence (NIH/OD) [E] (b) (6) ; Talley, Michael  
 (b) (6) >; Tsai, John (b) (6) ; Venkayya, Rajeev (b) (6) ;  
 Vessey, Rupert (b) (6) >; Virgin, Skip (b) (6) ; Wholley, David (FNIH) [T] (b) (6)  
 Woodcock, Janet (FDA/OC) < (b) (6) : Young, John (b) (6) >; Colvis,  
 Christine (NIH/NCATS) [E] (b) (6) >; Desrosiers, Betsy (b) (6) >; Eric  
 Hughes (b) (6) ; Jansen, Kathrin < (b) (6) Kurilla, Michael (NIH/NCATS) [E]  
 (b) (6) >; Lowy, Douglas (NCI) <d (b) (6) Read, Sarah (NIH/NIAID) [E] (b) (6)  
 Young, John (b) (6) >; Adam, Stacey (FNIH) [T] (b) (6) Margaret Anderson  
 (b) (6) >; Appell, Evan < (b) (6) . Chen, Helen (b) (6)  
 Connelly, Sarah (b) (6) >; Dally, Nicole (b) (6) Gonzalez, Nina  
 < (b) (6) Hawk, Harrison < (b) (6) Mendelson, Jesse <imendel (b) (6)  
 Menetski, Joseph (FNIH) [T] (b) (6) ; Nasr, Hana < (b) (6) Santos, Michael (FNIH) [T]  
 (b) (6) Sorosa, Alex (b) (6) >; Stratton, Benjamin < (b) (6) Tolman,  
 Brett < (b) (6) Wachtel, Jonathan (b) (6) >; Wholley, David (FNIH) [T]  
 (b) (6) ; Plump, Andrew (b) (6)  
**Cc:** Anderson, James (NIH/OD) [E] (b) (6) >; Burklow, John (NIH/OD) [E] (b) (6) ;  
 Carluccio, Dana < (b) (6) Castillejos, Carlos < (b) (6) ; FNIH Central Account  
 (b) (6) : Lumsden, Joanne (NIH/NCATS) [C] (b) (6) >; Hallett, Adrienne  
 (NIH/OD) [E] < (b) (6) Meltzer, Abbey (FNIH) [T] (b) (6) Myles, Renate (NIH/OD) [E]  
 (b) (6) >; Wolinetz, Carrie (NIH/OD) [E] < (b) (6)

**Subject:** Notes from Wednesday's ACTIV Leadership Team Meeting

Dear Leadership Team members and meeting attendees:

Please see the notes from our teleconference this past Wednesday, February 17. Please let me know of any additional comments, questions, or suggestions regarding these notes.

Thank you again for all your support of and contributions to ACTIV.

Regards,

David

David Wholley  
 Senior Vice-President, Research Partnerships  
 Foundation for the National Institutes of Health  
 (b) (6)

[dmw@fnih.org](mailto:dmw@fnih.org)  
 11400 Rockville Pike Suite 600 North Bethesda, MD 20852

*In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.*

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disclose or forward all or any of its contents. Please immediately notify the sender and thereafter delete this email and any attachments.

**Sent:** 9/9/2020 9:11:44 PM  
**To:** Chen, Helen Q. [ (b) (6) ]  
**CC:** Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]  
**Subject:** RE: ACTIV Therapeutics-Clinical Working Group Meeting

Hi Helen,

The hover over doesn't work in the PDF document but this will work when you display in presentation mode during the meeting tomorrow (agents in the hover over are those listed on CT.gov).

We (OD) will work with a developer when this goes live on the ACTIV website to ensure the feature will work.

-----Original Message-----

**From:** Chen, Helen Q. < (b) (6) >  
**Sent:** Wednesday, September 9, 2020 4:11 PM  
**To:** Parker, Ashley (NIH/OD) [E] < (b) (6) >  
**Cc:** Adam, Stacey (FNIH) [T] < (b) (6) > Santos, Michael (FNIH) [T] < (b) (6) > Appell, Evan < (b) (6) >  
**Subject:** FW: ACTIV Therapeutics-Clinical Working Group Meeting

Hi Ashley,

Please see below a question from Neil. My understanding is it will be a feature once it's live on the website - is that correct? Please feel free to provide any additional information / clarification that would help address Neil's inquiry. Thank you!

Warm regards,  
Helen

-----Original Message-----

**From:** Aggarwal, Neil (NIH/NHLBI) [E] < (b) (6) >  
**Sent:** Wednesday, September 9, 2020 4:07 PM  
**To:** Chen, Helen Q. < (b) (6) >  
**Subject:** [EXT] RE: ACTIV Therapeutics-Clinical Working Group Meeting

Thanks Helen. This has the potential to be a really useful document. At this point, should we be able to see agent information if we hover over the black circle with an A in it? If so, that feature does not seem to be working (at least not for me).

Best,  
Neil

Neil Aggarwal, MD  
Chief, Lung Biology and Disease Branch  
Division of Lung Diseases / NHLBI / NIH

-----Original Message-----

**From:** Chen, Helen Q. < (b) (6) >  
**Sent:** Wednesday, September 9, 2020 1:27 PM  
**To:** Adam, Stacey (FNIH) [T] < (b) (6) > Bozzette, Sam (NIH/NCATS) [E] < (b) (6) >  
Butterton, Joan < (b) (6) > De Claro, R. Angelo (FDA/CDER) < (b) (6) >  
Drachia-Akli, Ruxandra < (b) (6) > Eisner, Mark < (b) (6) > Gottesdiener, Keith < (b) (6) >  
< (b) (6) > Eric Hughes < (b) (6) > > Judy Currier  
< (b) (6) > Kim, Elizabeth < (b) (6) > LaVange, Lisa < (b) (6) >  
< (b) (6) > Mellors, John W < (b) (6) > Menon, Sandeep  
< (b) (6) > Parker, Ashley (NIH/OD) [E] < (b) (6) > Patel, Nainish  
< (b) (6) > Peppercorn, Amanda < (b) (6) > Poole, Mike  
< (b) (6) > Proschan, Michael (NIH/NIAID) [E] < (b) (6) > Read, Sarah  
(NIH/NIAID) [E] < (b) (6) > Santos, Michael (FNIH) [T] < (b) (6) > Shen, Yuan Li  
(FDA/CDER) < (b) (6) > ; Stein, Peter (FDA/CDER) < (b) (6) > Wholley, David  
(FNIH) [T] < (b) (6) > ; Buchman, Tim (OS/ASPR/BARDA) (CTR) < (b) (6) > Collins, Sylvia  
(FDA/CDER) < (b) (6) > Amanda Peppercorn <amanda. (b) (6) > Garner, Carl  
< (b) (6) > Hinds, Elizabeth (NIH/NIAID) [E] <ehinds@niaid.nih.gov>; Koroshetz, Walter  
(NIH/NINDS) [E] < (b) (6) > .gov>; Timothy Burgess < (b) (6) > Reineck, Lora



(NIH/NHLBI) [E] < (b) (6) Aggarwal, Neil (NIH/NHLBI) [E] < (b) (6)  
 Rosenberg, Yves (NIH/NHLBI) [E] < (b) (6) Goff, David (NIH/NHLBI) [E]  
 < (b) (6) Brown, Jeremy (NIH/NINDS) [E] < (b) (6) Gadbois, Ellen (NIH/OD) [E]  
 < (b) (6) Culp, Michelle (NIH/OD) [E] < (b) (6) Jacqueline Kirchner  
 < (b) (6) Beigel, John (NIH) [E] < (b) (6) Phillips, L  
 Revell CIV DTRA RD (USA) < (b) (6) >; Petrovick, Martha 0449 MITLL  
 < (b) (6) Sizemore, Christine (NIH/FIC) [E]  
 < (b) (6)  
 CC: Colvis, Christine (NIH/NCATS) [E] < (b) (6) Desrosiers, Betsy  
 (b) (6) >; Jansen, Kathrin < (b) (6) Kurilla, Michael  
 (NIH/NCATS) [E] < (b) (6) Lowy, Douglas (NCI) < (b) (6) Young, John  
 < (b) (6) Biggs, Mary < (b) (6) Butcher, Tina < (b) (6)  
 Demarcus < (b) (6) Macone, Erin < (b) (6) Melencio, Cheryl (FNIH) [T]  
 < (b) (6) Salathin, Carla < (b) (6) Tountas, Karen (FNIH) [T]  
 < (b) (6) Menetski, Joseph (FNIH) [T] < (b) (6) James, Stephanie (FNIH) [T]  
 < (b) (6) Wachtel, Jonathan < (b) (6) Tolman < (b) (6) Alvarez,  
 Rosa Maria < (b) (6) Gonzalez, Nina < (b) (6) Dana Carluccio  
 < (b) (6) Rose Li Central Account < (b) (6) Margaret  
 Anderson < (b) (6) Lucas Smalldon < (b) (6) Stratton,  
 Benjamin < (b) (6) Mollica, Linda /US  
 < (b) (6) Qashu, Felicia (NIH/OD) [E] < (b) (6) Patterson, Amy  
 (NIH/NHLBI) [E] < (b) (6) Rubin, Daniel B. (FDA/CDER) < (b) (6) Marston,  
 Hilary (NIH/NIAID) [E] < (b) (6) Wung, Peter /US < (b) (6) Hoots, W. Keith  
 (NIH/NHLBI) [E] < (b) (6) Groesch, Mary (NIH/NHLBI) [E] < (b) (6) Shipp,  
 Allan (NIH/NHLBI) [E] < (b) (6) Kindzelski, Andrei (NIH/NHLBI) [E]  
 < (b) (6) Hone, David M (Dave) CIV DTRA J9 (USA) < (b) (6)  
 Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) < Ronald. (b) (6) Freire, Maria (FNIH)  
 [T] < (b) (6) Elsaid, Olivia < (b) (6) Appell, Evan < (b) (6)  
 Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting

Dear ACTIV TX-Clinical Working Group Members,

As we have discussed previously, NIH has developed a table to summarize ACTIV and other NIH-supported COVID 19 trials. The goal of the table is to be informative to ACTIV and NIH leadership and to be shared more broadly once the information within it is public.

We would appreciate your review of this draft version of the table, which we are sharing ahead of tomorrow's Working Group meeting. Please do not share the table or the information in it further. We are looking forward to your input.

Warm regards,  
 Stacey, Mike, and Helen

-----Original Appointment-----

From: Adam, Stacey (FNIH) [T] < (b) (6)  
 Sent: Wednesday, June 17, 2020 8:48 AM  
 To: Adam, Stacey (FNIH) [T]; Bozette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John W; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6) Sizemore, Christine (NIH/FIC) [E]  
 CC: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa Maria; Gonzalez, Nina; Dana Carluccio. Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia  
 Subject: ACTIV Therapeutics-Clinical Working Group Meeting  
 When: Thursday, September 10, 2020 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).  
 Where: <https://secure.web.cisco> (b) (6)

Stacey Adam is inviting you to a scheduled Zoom meeting.



Join Zoom Meeting  
<https://secure-web.cisco>

(b) (6)

Meeting ID: (b) (6)  
Password: (b) (6)  
One tap mobile

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US (Chicago)

Dial by your location  
(b) (6)

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US (Chicago)  
US (New York)  
US (Tacoma)  
US (Houston)  
US (San Jose)  
US (San Jose)

Meeting ID: (b) (6)  
Password: 169608  
Find your local number: <https://secure-web.cisco.com/>

(b) (6)

(b) (6)

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**From:** Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]  
**Sent:** 4/16/2020 12:03:08 PM  
**To:** Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]  
**CC:** Wolinetz, Carne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]  
**Subject:** RE: PLEASE READ Draft Email to Collect Communication Contact Information

Good morning Renate,

Our rep at Takeda, Andy Plump is included on the master list. I am confirming with Francis that he used our master list for his email that went out last night – **I should be able to confirm this for you this morning.**

I hope you are staying safe and healthy; maybe even getting some rest in between the constant COVID activities.

Thanks,  
Ashley

**From:** Myles, Renate (NIH/OD) [E] <(b) (6)>  
**Sent:** Thursday, April 16, 2020 7:14 AM  
**To:** Parker, Ashley (NIH/OD) [E] <(b) (6)>  
**Cc:** Wolinetz, Carrie (NIH/OD) [E] <(b) (6)>  
**Subject:** FW: PLEASE READ: Draft Email to Collect Communication Contact Information  
**Importance:** High

Hi Ashley:

I'm not sure if Francis added a Takeda contact to his email. I could not find one on the master contact list. I have not heard from their organizations yet. Would you let me know if you provided that to him last night or if they are missing from this email? Need to send it to this group this morning.

Thanks,  
Renate

**From:** Myles, Renate (NIH/OD) [E]  
**Sent:** Wednesday, April 15, 2020 9:11 PM  
**To:** Collins, Francis (NIH/OD) [E] <(b) (6)>  
**Cc:** Wood, Gretchen (NIH/OD) [E] <(b) (6)> >; McManus, Ayanna (NIH/OD) [E] <(b) (6)> >; Burklow, John (NIH/OD) [E] <(b) (6)> Parker,  
Ashley (NIH/OD) [E] <(b) (6)>  
**Subject:** PLEASE READ: Draft Email to Collect Communication Contact Information  
**Importance:** High

Hi Francis:

We need to collect the communication contacts from the partner organizations so we can share the release with them for review. Below is 1) a draft email for you to send to the company participants, 2) the contacts for the companies we list in the release except for Takeda (I could not find a Takeda contact on the master list; hoping Ashley can provide); 3) those who should be copied (feel free to add others).

Dear ACTIV colleagues:

As I mentioned earlier today, we would like to announce the plans for a public-private partnership as expeditiously as possible. Please provide the name of the most appropriate communication contact from your company so that we may share a draft of the embargoed press release for your review. Please send the contact information to Renate Myles at (b) (6) and Abbey Meltzer ( (b) (6) ) this evening, if possible.

BCC:

(b) (6)

CC:

(b) (6)

Thanks,  
Renate

**From:** Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]  
**Sent:** 7/14/2020 12:51:27 AM  
**To:** Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]  
**Subject:** Re: ACTIV Clinical Trial Capacity Working Group - reporting meeting  
**Attachments:** Clinical Trial Capacity Working Group Meeting Agenda 07142020 pdf; ATT00001.htm  
**Location:** <https://fnih.zoom.us>, (b) (6)  
**Start:** 7/14/2020 1:00:00 PM  
**End:** 7/14/2020 2:00:00 PM  
**Show Time As:** Tentative

Hi Lauren,

I often have a conflict with this Clinical trial capacity WG meeting are you free to join 9-10am tomorrow in listen mode? If so, could you take notes and track any information on the playbooks the WG will report tomorrow? We include information about this on the draft webpage and should be a useful update.

Thanks,  
Ashley

Begin forwarded message:

**From:** "Tountas, Karen (FNIH) [T]" <(b) (6)>  
**To:** "Bascles, Lionel" <(b) (6)> "Cohen, Myron" <(b) (6)>  
<myron (b) (6)> "Corey, Larry" <(b) (6)> "Victoria Davey" <(b) (6)>  
<(b) (6)> "Desrosiers, Betsy" <(b) (6)> "Dickens, Jim (NIH/NCATS) [C]" <(b) (6)> >, "Doroshov, James (NIH/NCI) [E]" <(b) (6)>  
>, "Garner, Carlos" <(b) (6)> "Goff, David (NIH/NHLBI) [E]" <(b) (6)>  
>, "Kurilla, Michael (NIH/NCATS) [E]" <(b) (6)> >, "Mensah, George (NIH/NHLBI) [E]" <(b) (6)> ,  
"Nayak, Seema (NIH/NIAID) [E]" <(b) (6)> "Payton, Manizhe (NIH/NIAID) [E]" <(b) (6)>  
"Resnansky, Laura" <(b) (6)> "Sizemore, Christine (NIH/FIC) [E]" <(b) (6)> >, "Srinivasan, Badhri" <(b) (6)>  
<(b) (6)> "Stein, Peter (FDA/CDER)" <(b) (6)>  
"Takas, Therese" <(b) (6)> >, "Vincent, Mike" <(b) (6)>  
<(b) (6)> , "Weinmann, Gail (NIH/NHLBI) [E]" <(b) (6)>  
<(b) (6)> >, "Stratton, Ben" <(b) (6)>  
**Cc:** "Wachtel, Jonathan" <(b) (6)> , "Colvis, Christine (NIH/NCATS) [E]" <(b) (6)>  
<(b) (6)> , "Hughes, Eric" <(b) (6)> "Jansen, Kathrin" <(b) (6)>  
<(b) (6)> "Lowy, Douglas (NCI)" <(b) (6)> "Read, Sarah (NIH/NIAID) [E]" <(b) (6)>  
>, "Young, John" <(b) (6)> "Ardiff, Bernadette" <(b) (6)>  
>, "Criffield, Robin" <(b) (6)>  
>, "Hamilton, Nancy" <(b) (6)>  
"Melencio, Cheryl (FNIH) [T]" <(b) (6)> "Minnich, Beth" <(b) (6)>  
<(b) (6)> "Mueller-Reichenstein, Petra" <petra.mueller- (b) (6)>  
"Pico, Dianna (NIH/NHLBI) [C]" <(b) (6)>

"Quadros, Nora" (b) (6) >, "Katz, Rebecca (NIH/NCATS) [E]"  
 (b) (6) , "Hill, Zoe (NIH/NHLBI) [C]" < (b) (6) "Adam, Stacey  
 (FNIH) [T]" < (b) (6) "Anderson, Margaret" < (b) (6)  
 "Parker, Ashley (NIH/OD) [E]" < (b) (6) "Carluccio, Dana"  
 < (b) (6) >, "Culp, Michelle (NIH/OD) [E]"  
 (b) (6) "Gadbois, Ellen (NIH/OD) [E]" < (b) (6)  
 "Gonzalez, Nina" < (b) (6) "Heaton, Penny"  
 < (b) (6) "James, Stephanie (FNIH) [T]" < (b) (6) "Kenny,  
 Dermot" < (b) (6) >, "Kublin, James" (b) (6) , "Li, Rose"  
 < (b) (6) "Menetski, Joseph (FNIH) [T]" (b) (6) , "Qashu,  
 Felicia (NIH/OD) [E]" < (b) (6) "Santos, Michael (FNIH) [T]"  
 < (b) (6) "Tuvevsson, Nancy" (b) (6) , "Wholley,  
 David (FNIH) [T]" < (b) (6) "Elsaid, Olivia" < (b) (6)

**Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting**

Dear WG members; During this call we will share some exciting updates regarding the development of the 'playbooks'; and we will have an important discussion about updating the site survey for NCATS. Looking forward to the call and hope you can make it! Karen

Dear Clinical Trial Capacity Working group members - As the tiger teams continue to work closely with ACTIV protocol development and operations teams, and the 'playbook' development teams ramp up to quickly develop these resources, we will reduce the number of times the full WG meets in July to every other week (July 14th and 28th). Best, Karen

Karen Tountas is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

<https://fnih.zoom.us/j/>

(b) (6)

Meeting ID: (b) (6)

Password: (b) (6)

One tap mobile

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US (Chicago)

US (New York)

Dial by your location

(b) (6)

US (Chicago)

US (New York)

US (Germantown)

US (Tacoma)

US (Houston)

US (San Jose)

US (San Jose)

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://fnih.zoom.us/j/> (b) (6)

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(b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan]; Beth Bell  
(b) (6) [ (b) (6) (b) (6) (b) (6) Cavaleri Marco  
(b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Haynes,  
Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002.mc]; hotez@bcm.edu;  
(b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John  
(NIH/VR) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Messonnier, Nancy  
(CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Nelson Michael  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c3323ab6a02468689fa2c51a87c43cc-NelsonMicha]; Offit, Paul  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb9cc56fdb4e598a57b423d484dcf9f-offit.email] (b) (6)  
Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccb4e3caaf5eb5d3586b1cc-Jonathan.Se];  
(b) (6) (b) (6) Tal Zaks [ (b) (6)  
**CC:** Tolman, Brett [ (b) (6) (b) (6) Hopps, Markay [ (b) (6)  
Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Johnson, Maureen  
(NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr];  
(b) (6) Jeneffer Haynes [ (b) (6) ]; (b) (6)  
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(b) (6) Isabel Ramsey [ (b) (6) ]; Parker, Ashley (NIH/OD) [E]  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Marston, Hilary  
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Qashu, Felicia (NIH/OD)  
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Culp, Michelle (NIH/OD)  
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E]  
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[T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskiup]; Adam, Stacey (FNIH) [T]  
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John  
(b) (6) Paul Gillard [ (b) (6) Hamilton, Holli (OS/ASPR/BARDA)  
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USARMY MEDCOM WRAIR (USA) [ (b) (6) Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange  
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.com];  
Schrage, Stephanie (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=9be29b344ba14363bdecaa43582ca226-ZHA6]; Verani, Jennifer R.  
(CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7c249692151d46d6ac80cb28ada3d3a0-qzr7]; Thornburg, Natalie  
(CDC/DDID/NCIRD/DVD) [/o=ExchangeLabs/ou=Exchange Administrative Group  
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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];  
'Wachtel, Jonathan' [ (b) (6) Stratton, Benjamin [ (b) (6) Anderson, Margaret  
[ (b) (6) (b) (6) Bethany Stokes  
[ (b) (6) Kathleen Callahan [ (b) (6) Molloy, Delia (DPH)  
[ (b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=001a98d300d14b20b18c01181eb843e0-Arvinam.Sta]; Jacqueline Miller  
[ (b) (6) Kayvon Modjarrad [ (b) (6)

**Subject:** Canceled: ACTIV Vaccines Working Group meeting  
**Location:** Webex: <https://nih.webex.com/nih>, (b) (6)

**Start:** 7/8/2020 5:15:00 PM  
**End:** 7/8/2020 6:15:00 PM  
**Show Time As:** Free

**Required Attendees:** (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6) Arvin, Ann; Beth Bell  
(b) (6) (b) (6) Cavaleri Marco; (b) (6)  
(b) (6) (b) (6) Greg Glenn; (b) (6) Haynes,  
Barton; (b) (6) (b) (6) Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E];  
Messonnier, Nancy (CDC/DDID/NCIRD/OD); Nelson Michael; Offit, Paul; (b) (6) Seals, Jonathan  
(OS/ASPR/BARDA); (b) (6) tonya. (b) (6) Tal Zaks  
**Optional Attendees:** Tolman, Brett; (b) (6) Hopps, Markay, Kozlowsk, Mary (NIH/NCI) [C]; Johnson, Maureen  
(NIH/NCI) [E]; (b) (6) Jeneffer Haynes; (b) (6) (b) (6)  
(b) (6) Austin, Sarah (NIH/NIAID) [E]; (b) (6) Isabel Ramsey; Parker,  
Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E];  
Gadbois, Ellen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T];  
Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E];  
Desrosiers, Betsy, Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul  
Gillard; Hamilton, Holli (OS/ASPR/BARDA); Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA); Kathleen Neuzil;  
Schrage, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Thornburg, Natalie  
(CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin; Anderson, Margaret;  
(b) (6) (b) (6) Bethany Stokes; Kathleen Callahan; Molloy,  
Delia (DPH); Ann Arvin; Jacqueline Miller; Kayvon Modjarrad



**To:** Bozzette, Sam (NIH/NCATS) [E] [ (b) (6) Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adams;4];  
 Butters, Joan [ (b) (6) De Claro, R. Angelo (FDA/CDER) [ (b) (6) ];  
 Draghia-Ak i, Ruxandra [ (b) (6) Gottesdiener, Keith [ (b) (6) Eric Hughes  
 [ (b) (6) Judy Currier [ (b) (6) Kim, Elizabeth [ (b) (6)  
 LaVange, Lisa [ (b) (6) Mellors, John W [ (b) (6) ]; Menon, Sandeep  
 [ (b) (6) Parker, Ashley (NIH/OD) [E] [ (b) (6) ]; Patel, Naimish  
 [ (b) (6) Peppercorn, Amanda [ (b) (6) Poole, Mike  
 [ (b) (6) Proschan, Michael (NIH/NIAID) [E] [ (b) (6) Read, Sarah  
 (NIH/NIAID) [E] [ (b) (6) Santos, Michael (FNIH) [T] [ (b) (6) Shen, Yuan Li (FDA/CDER)  
 [ (b) (6) Stein, Peter (FDA/CDER) [ (b) (6) Wholley, David (FNIH) [T]  
 [ (b) (6) Buchman, Tim (OS/ASPR/BARDA) (CTR) [ (b) (6) Collins, Sylva (FDA/CDER)  
 [ (b) (6) ]; Amanda Peppercorn [ (b) (6) Higgs, Elizabeth (NIH/NIAID)  
 [E] [ (b) (6) .gov]; Koroshetz, Walter (NIH/NINDS) [E] [ (b) (6) Timothy Burgess  
 [ (b) (6) Reineck, Lora (NIH/NHLBI) [E] [ (b) (6) Aggarwal, Neil (NIH/NHLBI) [E]  
 [ (b) (6) Rosenberg, Yves (NIH/NHLBI) [E] [ (b) (6) Goff, David (NIH/NHLBI) [E]  
 [ (b) (6) ]; Brown, Jeremy (NIH/NINDS) [E] [ (b) (6) Gadbois, Ellen (NIH/OD) [E]  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadbois]; Culp, Michelle (NIH/OD)  
 [E] [ (b) (6) ]; Jacqueline Kirchner [ (b) (6) Beigel, John (NIH) [E]  
 [ (b) (6) ]; Phillips, L Revell CIV DTRA RD (USA) [ (b) (6) Petrovick, Martha - 0449 -  
 MITLL [ (b) (6) (b) (6) Sizemore, Christine (NIH/FIC) [E]  
 [ (b) (6) Larry Tsai [ (b) (6) Wung, Peter K [ (b) (6) Garner,  
 Carl [ (b) (6) Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative  
 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Levy, Elliot  
 [ (b) (6)

**CC:** Colvis, Christine (NIH/NCATS) [E] [ (b) (6) ]; Jansen, Kathrin [ (b) (6) Lowy,  
 Douglas (NCI) [ (b) (6) ]; Young, John [ (b) (6) Biggs, Mary [ (b) (6)  
 Butcher, Tina [ (b) (6) Demarcus [ (b) (6) Macone, Erin  
 [ (b) (6) Melencio, Cheryl (FNIH) [T] [ (b) (6) Salathin, Carla  
 [ (b) (6) Menetski, Joseph (FNIH) [T] [ (b) (6) Dana Carluccio  
 [ (b) (6) Rose Li Central Account [ (b) (6) Lucas Smalldon  
 [ (b) (6) Mollica, Linda /US  
 [ (b) (6) Qashu, Felicia (NIH/OD) [E] [ (b) (6) Patterson, Amy (NIH/NHLBI) [E]  
 [ (b) (6) Rubin, Daniel B. (FDA/CDER) [ (b) (6) Marston, Hilary (NIH/NIAID) [E]  
 [ (b) (6) Chen, Helen Q. [ (b) (6) Hoots, W. Keith (NIH/NHLBI) [E]  
 [ (b) (6) Groesch, Mary (NIH/NHLBI) [E] [ (b) (6) Shipp, Alan (NIH/NHLBI) [E]  
 [ (b) (6) Kindzelski, Andrei (NIH/NHLBI) [E] [ (b) (6) Hone, David M (Dave) CIV  
 DTRA J9 (USA) [ (b) (6) Reiser, Rona d B CTR USARMY DOD JPEO CBRND (USA)  
 [ (b) (6) Walker, Paula (NIH/NINDS) [E] [ (b) (6) Sorosa, Alex David  
 [ (b) (6) Lumsden, Joanne (NIH/NCATS) [C] [ (b) (6) ]; Lerner, Andrea (NIH/NIAID)  
 [E] [andrea [ (b) (6) Embry, Alan (NIH/NIAID) [E] [ (b) (6) Dally, Nicolle  
 [ (b) (6)

**Start:** 4/22/2021 5:00:00 PM  
**End:** 4/22/2021 6:00:00 PM

**Recurrence:** (none)

**From:** Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]  
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(b) (6) Lowy, Douglas (NIH/NCI) [E] [ (b) (6) ]; (b) (6)  
Arvin, Ann [ (b) (6) Beth Bell [ (b) (6) [ (b) (6)  
(b) (6) Cavaleri Marco [ (b) (6) (b) (6)  
(b) (6) (b) (6) Greg Glenn [ (b) (6)  
(b) (6) Haynes, Barton [ (b) (6) (b) (6) (b) (6)  
Marks, Peter (FDA/CBER) [ (b) (6) Mascola, John (NIH/VRC) [E] [ (b) (6)  
Messonnier, Nancy (CDC/DDID/NCIRD/OD) [ (b) (6) Nelson Michael [nelson. (b) (6)  
Offit, Paul [ (b) (6) (b) (6) Seals, Jonathan (OS/ASPR/BARDA)  
[ (b) (6) (b) (6) (b) (6) Tal Zaks  
(b) (6)  
**CC:** Tolman, Brett [ (b) (6) ]; (b) (6) Hopps, Markay [ (b) (6)  
Kozlowski, Mary (NIH/NCI) [C] [ (b) (6) Johnson, Maureen (NIH/NCI) [E]  
[ (b) (6) (b) (6) Jeneffer Haynes [ (b) (6) ],  
(b) (6) kell (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E]  
[austinsj@niaid.nih.gov]; (b) (6) Isabel Ramsey [ (b) (6) Parker,  
Ashley (NIH/OD) [E] [ (b) (6) Marston, Hilary (NIH/NIAID) [E] [ (b) (6) ]; Qashu,  
Felicia (NIH/OD) [E] [fei (b) (6) Culp, Michelle (NIH/OD) [E] [ (b) (6) Gadbois, Ellen  
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Wholley, David (FNIH) [T]  
[ (b) (6) Melencio, Cheryl (FNIH) [T] [ (b) (6) Menetski, Joseph (FNIH) [T]  
[ (b) (6) Adam, Stacey (FNIH) [T] [ (b) (6) Tountas, Karen (FNIH) [T] [ (b) (6)  
James, Stephanie (FNIH) [T] [ (b) (6) Co-vis, Christine (NIH/NCATS) [E] [ (b) (6)  
Desrosiers, Betsy [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [ (b) (6)  
Read, Sarah (NIH/NIAID) [E] [ (b) (6) Paul Gillard [ (b) (6) Hamilton, Holli  
(OS/ASPR/BARDA) (b) (6) Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA)  
(b) (6) Kathleen Neuzil [ (b) (6) Schrag, Stephanie  
(CDC/DDID/NCIRD/DBD) [ (b) (6) Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) [ (b) (6)  
Thornburg, Natalie (CDC/DDID/NCIRD/DVD) [ (b) (6) Gonzalez, Nina [ (b) (6) 'Wachtel,  
Jonathan' [ (b) (6) Stratton, Benjamin [ (b) (6) Anderson, Margaret  
[ (b) (6) (b) (6) (b) (6) Bethany Stokes  
[ (b) (6) Kathleen Callahan [ (b) (6) Arvin, Ann  
[ (b) (6) Cohen, Myron [ (b) (6) (b) (6) Erbelding, Emily  
(NIH/NIAID) [E] [ (b) (6) ]; (b) (6) (b) (6) Gruber, Marion  
(FDA/CBER) [ (b) (6) ]; (b) (6) Kenneth. (b) (6)  
Ledgerwood, Julie (NIH/NIAID) [E] [ (b) (6) ]; (b) (6) Marovich, Mary (NIH/NIAID)  
[E] [mary.marovich@nih.gov]; Merlin Robb [ (b) (6) (b) (6) Laurent Humeau  
[ (b) (6) (b) (6) (b) (6) Gebo, Kelly (NIH/OD) [G]  
[ (b) (6) ]; Jacqueline Miller [ (b) (6) (b) (6) Sitar,  
Sandra (NIH/VRC) [C] [ (b) (6) Tong, Tina (NIH/NIAID) [E] [ (b) (6) Sridhar, Saranya /US  
(b) (6) ; Brian Rosen [ (b) (6) Cheryl Keech [ (b) (6) Sadoff,  
Jerald [JRDUS] [ (b) (6) Michael, Nelson [ (b) (6) Kayvon Modjarrad  
(b) (6) ; Hughes, Eric (b) (6) ; Young, John [ (b) (6)  
**Subject:** ACTIV Vaccines Working Group meeting  
**Location:** Webex: <https://nih.webex.com> (b) (6)  
**Start:** 7/1/2020 2:30:00 PM  
**End:** 7/1/2020 3:30:00 PM  
**Show Time As:** Tentative

**Required Attendees:** (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6) Arvin, Ann; Beth Bell  
 (b) (6) Cavaleri Marco, (b) (6)  
 (b) (6) Greg Glenn; (b) (6) Haynes,  
 Barton, (b) (6) Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E],  
 Messonnier, Nancy (CDC/DDID/NCIRD/OD); Nelson Michael; Offit, Paul; (b) (6) .com; Seals, Jonathan  
 (OS/ASPR/BARDA); (b) (6) Tal Zaks  
**Optional Attendees:** Tolman, Brett; (b) (6) Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen  
 (NIH/NCI) [E]; (b) (6) Jeneffer Haynes; (b) (6) (b) (6)  
 (b) (6) Austin, Sarah (NIH/NIAID) [E]; (b) (6) Isabel Ramsey; Parker,  
 Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E], Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E];  
 Gadbois, Ellen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T];  
 Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T], James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E];  
 Desrosiers, Betsy, Hughes, Eric; Kurla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul  
 Gillard; Hamilton, Hollie (OS/ASPR/BARDA); Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA); Kathleen Neuzil;  
 Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Thornburg, Natalie  
 (CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin; Anderson, Margaret;  
 (b) (6) ; Bethany Stokes; Kathleen Callahan; Ann Arvin;  
 Cohen, Myron; (b) (6) Erbelding, Emily (NIH/NIAID) [E]; (b) (6)  
 Bill. (b) (6) Gruber, Marion (FDA/CBER); (b) (6) (b) (6)  
 Ledgerwood, Julie (NIH/NIAID) [E]; (b) (6) .com; Marovich, Mary (NIH/NIAID) [E]; Merlin Robb;  
 (b) (6) Laurent Humeau; Peter Dul (b) (6) (b) (6)  
 Gebo, Kelly (NIH/OD) [G]; Jacqueline Miller; robin\_criffield@med.unc.edu; Sitar, Sandra (NIH/VRC) [C]; Tong, Tina  
 (NIH/NIAID) [E]; Sridhar, Saranya /US; Brian Rosen; Cheryl Keech; Sadoff, Jerald [JRDUS]; Michael, Nelson; Kayvon  
 Modjarrad

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### Join from a video system or application

Dial (b) (6)

You can also dial (b) (6) and enter your meeting number.

### Join by phone

Tap to call in from a mobile device (attendees only)

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Global call-in numbers

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or <https://www.webex.com>

If you are a host, [click here to view host information.](#) **IMPORTANT:**

**From:** Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
**Sent:** 1/7/2021 4:37:47 PM  
**To:** Garner, Carl [ (b) (6) Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [ (b) (6) Eisner, Mark [ (b) (6) Gottesdiener, Keith [ (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [ (b) (6) LaVange, Lisa [ (b) (6) Levy, Elliot [ (b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [naimish. (b) (6) Peppercorn, Amanda [ (b) (6) Poole, Mike [ (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia Colli]; Amanda Peppercorn [ (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [ (b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV

CC: DTRA RD (USA) [ (b) (6) Petrovick, Martha - 0449 - MITLL [ (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Jansen, Kathrin [ (b) (6) Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [ (b) (6) Biggs, Mary [ (b) (6) Butcher, Tina [ (b) (6) Demarcus [ (b) (6) Macone, Erin [ (b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [ (b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskiip]; Dana Carluccio [ (b) (6) Rose Li Central Account [ (b) (6) Lucas Smalldon [ (b) (6) Mollica, Linda /US [ (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, H Mary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Wung, Peter /US [ (b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [ (b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) [ (b) (6) Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact\_f12]; Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]

**Subject:** ACTIV Therapeutics-Clinical Working Group

**Attachments:** ACTIV\_TX-Clinical WG Meeting\_20210107.pdf

**Location:** <https://fnih.zoom.us/> (b) (6)

**Start:** 1/7/2021 6:00:00 PM

**End:** 1/7/2021 7:00:00 PM

**Show Time As:** Tentative

**Recurrence:** Weekly  
every Thursday from 1:00 PM to 2:00 PM

**Required Attendees:** Garner, Carl; Bozette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth, LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylvia (FDA/CDER); Amanda Peppercorn; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E];



Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6)  
Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner;  
Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovck, Martha - 0449 - MITLL;  
(b) (6) Sizemore, Christine (NIH/FIC) [E]

**Optional Attendees:** Colvis, Christine (NIH/NCATS) [E]; Jansen, Kathrin; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina;  
Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Menetski, Joseph (FNIH) [T]; Dana Cariuccio;  
Rose Li Centra Account; Lucas Sma Idon; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD)  
[E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.;  
Wung, Peter /US; Hoots, W Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E];  
Kindzeiski, Andre (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD  
JPEO CBRND (USA); Walker, Paula (NIH/NINDS) [E]; Sorosa, Alex David; Lumsden, Joanne (NIH/NCATS) [C]

Dear ACTIV TX-Clinical WG,

Happy New Year! I look forward to seeing most of you today!  
Please find attached the slides for today's meeting.

Thanks,  
Stacey

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**From:** Cat Lutz [ (b) (6) ]  
**Sent:** 10/28/2020 12:57:08 PM  
**To:** Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6)  
(b) (6) Annaliesa. (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; (b) (6)  
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];  
(b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkera]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];  
(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [ (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [ (b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [ (b) (6) Puntuneri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-puntuneria]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6)  
**CC:** Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [ (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim, Elizabeth [ (b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan (b) (6) Prabhavathi



Fernandes [ (b) (6) Diamond, Michael [ (b) (6) Rose Li  
 [ (b) (6) Dana Carluccio [ (b) (6) Lagos, Enrique (NIH/NCATS)  
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagosel]; Jonson, Samantha  
 (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];  
 Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi  
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=Sbbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D  
 [ (b) (6) Dave Frankowski [ (b) (6) Baric, Toni C  
 [ (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative  
 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowydl]; Florence, Clint  
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoonoh]; Stratton, Benjamin  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188];  
 Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James  
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]

**Subject:** RE: ACTIV Preclinical full working group

Interesting paper on the S614G variant:

<https://www.biorxiv.org/content/10.1101/2020.10.27.357558v1>

Cathleen Lutz, Ph.D. MBA

Senior Director, Mouse Repository & In Vivo Pharmacology

Rare and Orphan Disease Center

(b) (6)

The Jackson Laboratory

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-----Original Appointment-----

**From:** Menetski, Joseph (FNIH) [T] < (b) (6)>

**Sent:** Tuesday, April 14, 2020 6:43 PM

**To:** Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E];

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Annaliesa.

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Baric, Ralph;

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Ottinger, Elizabeth (NIH/NCATS

[E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER);

(b) (6)

Cat Lutz;

(b) (6)

Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD)

[E]; (b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E];

Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette,

Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E];

(b) (6)

**Cc:** Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy;

Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E];

Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa

Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana

Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C];

Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski, Baric, Toni C; Lowy, Douglas (NIH/NCI) [E];

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Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]

**Subject:** [EXTERNAL]ACTIV Preclinical full working group

**When:** Wednesday, October 28, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

**Where:** <https://fnih.zoom.us/> (b) (6)

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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**Sent:** 7/18/2020 2:19:45 AM  
**To:** Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fid]; Draghia-Akli, Ruxandra [ (b) (6) Eisner, Mark [ (b) (6) Gottesdiener, Keith [ (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [ (b) (6) LaVange, Lisa [ (b) (6) Levy, Elliot [ (b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish (b) (6) Peppercorn, Amanda [ (b) (6) Poole, Mike [ (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia Colli]; Amanda Peppercorn [ (b) (6) Garner, Carl (b) (6) : Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dc8c847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [ (b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative

Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Philips, L Revell CIV DTRA RD (USA) [ (b) (6) Petrovick, Martha - 0449 - MITLL [ (b) (6) (b) (6)

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [ (b) (6) Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John (b) (6) Biggs, Mary [ (b) (6) Butcher, Tina [ (b) (6) Demarcus [ (b) (6) Macone, Erin [ (b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [ (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan (b) (6) Tolman, Brett [ (b) (6) Alvarez, Rosa [ (b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [ (b) (6) Rose Li Central Account [ (b) (6) Anderson, Margaret [ (b) (6) Lucas Smalldon [ (b) (6) Stratton, Benjamin [ (b) (6) Qashu, Felicia (NIH/OD) [E] (b) (6) Mollica, Linda /US [ (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. [ (b) (6) Wung, Peter /US [ (b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9b4f99383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2dbSc-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [ (b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) [ (b) (6)

**Subject:** ACTIV Therapeutics-Clinical Working Group Meeting

**Attachments:** 2020-07-16\_TX-Clinical\_WG\_Meeting\_Summary.pdf

Dear ACTIV Therapeutics-Clinical WG,

Please find attached the summary of yesterday's meeting. Please let me know if you have any additions or amendments to the document.

We will work to arrange some of the discussions noted in the ACTIV-4 section for the coming weeks.

Thanks,  
Stacey

**Stacey J. Adam, PhD**

Director, Cancer

Research Partnerships

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**From:** Charette, Marc (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A7FA2BAF951848B5BF1F76A049A0ECA6-CHARETTEMF]

**Sent:** 6/23/2020 1:24:30 PM

**To:** Alvarez, Rosa Maria [ (b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; (b) (6) Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Diamond, Michael [ (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [ (b) (6) Hughes, Eric [ (b) (6) Jansen, Kathryn [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kim, Elizabeth [ (b) (6) Tolman, Brett [ (b) (6) Wachtel, Jonathan [ (b) (6) Prabhavathi Fernandes [ (b) (6) Rose Li [ (b) (6) Dana Carluccio [ (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [ (b) (6) Dave Frankowski [ (b) (6) Baric, Toni C [ (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295f-florencewc]; Nancy Haigwood

[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon oh], Stratton, Benjamin  
[ (b) (6) Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];  
(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD)  
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];  
(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative  
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas  
[ (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar  
[ (b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [ (b) (6)  
Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Fessel, Josh (NIH/NHLBI)  
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]

**Subject:** RE: ACTIV Preclinical full working group

**Attachments:** ACTIV Pandemic Response Development Manuscript\_20200622 Abstract with MC suggestions 062320.docx

Hello everyone,

Perhaps it is too early, but I have made some suggested changes to the abstract.

Most are stylist but some are for readability.

Best,

**Marc Charette, Ph.D.**

Program Director

Vascular Biology and Hypertension Branch

Division of Cardiovascular Sciences

Director

Vascular Interventions/Innovations and Therapeutic Advances (VITA) Program



National Heart, Lung,  
and Blood Institute

6705 Rockledge Drive

Rockledge Center One, workspace 313M

Bethesda, MD 20892

(b) (6)

(b) (6)

**From:** Alvarez, Rosa Maria < (b) (6) >

**Sent:** Monday, June 22, 2020 6:55 PM

**To:** Menetski, Joseph (FNIH) [T] < (b) (6) > (b) (6) Hild, Sheri (NIH/OD) [E]

< (b) (6) > (b) (6) (b) (6) (b) (6)

(b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph

< (b) (6) > (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E]

< (b) (6) > Colvis, Christine (NIH/NCATS) [E] < (b) (6) > Hewitt, Judith (NIH/NIAID)



[E] < (b) (6) Culp, Michelle (NIH/OD) [E] < (b) (6) Gadbois, Ellen (NIH/OD) [E]  
 < (b) (6) Diamond, Michael < (b) (6) Wholley, David (FNIH) [T] < (b) (6)  
 Austin, Christopher (NIH/NCATS) [E] < (b) (6) Melencio, Cheryl (FNIH) [T] < (b) (6)  
 Desrosiers, Betsy < (b) (6) Hughes, Eric < (b) (6) Jansen, Kathrin  
 < (b) (6) Kurilla, Michael (NIH/NCATS) [E] < (b) (6) Lowy, Douglas (NCI)  
 < (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6) Tountas, Karen (FNIH) [T] < (b) (6)  
 Santos, Michael (FNIH) [T] < (b) (6) Adam, Stacey (FNIH) [T] < (b) (6) James, Stephanie (FNIH)  
 [T] < (b) (6) Kim, Elizabeth < (b) (6) Tolman, Brett < (b) (6) Wachtel,  
 Jonathan < (b) (6) Prabhavathi Fernandes < (b) (6) Rose Li  
 < (b) (6) Dana Carluccio < (b) (6) Lagos, Enrique (NIH/NCATS) [E]  
 < (b) (6) Jonson, Samantha (NIH/NCATS) [E] < (b) (6) Gonzalez, Nina  
 < (b) (6) Simon, Dina (NIH/OD) [C] < (b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E]  
 < (b) (6) Rodriguez, Robin D < (b) (6) Dave Frankowski  
 < (b) (6) Baric, Toni C < (b) (6) Lowy, Douglas (NIH/NCI) [E]  
 < (b) (6) Florence, Clint (NIH/NIAID) [E] < (b) (6) Nancy Haigwood  
 < (b) (6) Stratton, Benjamin < (b) (6) Deming, Damon (FDA/CDER)  
 < (b) (6) (b) (6) (b) (6) (b) (6) Parker,  
 Ashley (NIH/OD) [E] < (b) (6) Collins, Francis (NIH/OD) [E] < (b) (6)  
 (b) (6) Adams, Peter (OS/ASPR/BARDA) < (b) (6) Rao, Srinivas  
 < (b) (6) Qashu, Felicia (NIH/OD) [E] < (b) (6) Tomas Cihlar  
 < (b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) < (b) (6)  
 Punturieri, Antonello (NIH/NHLBI) [E] < (b) (6) Charette, Marc (NIH/NHLBI) [E]  
 < (b) (6) Fessel, Josh (NIH/NHLBI) [E] < (b) (6)

**Subject:** RE: ACTIV Preclinical full working group

Hi all,

Apologies – We sent an earlier version of the abstract. Attached for the latest abstract of the Pandemic Response Drug Development Manuscript.

Please let us know if you have any feedback.

Best regards,  
 Rosa

**Rosa M. Álvarez**  
 Deloitte Consulting LLP  
 Mobile: (b) (6)  
[www.deloitte.com](http://www.deloitte.com)

-----Original Appointment-----

**From:** Menetski, Joseph (FNIH) [T] <(b) (6)>  
**Sent:** Tuesday, April 14, 2020 6:44 PM  
**To:** Menetski, Joseph (FNIH) [T]; (b) (6); Hild, Sheri (NIH/OD) [E] (b) (6)  
 (b) (6) (b) (6) (b) (6) (b) (6)  
 (b) (6); Baric, Ralph; (b) (6); Ottinger, Elizabeth (NIH/NCATS)  
 [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER);  
 (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis  
 (NIH/OD) [E]; (b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD)  
 [E]; Tomas Cihlar, Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E];  
 Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]  
**Cc:** Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Diamond, Michael; Wholley, David (FNIH) [T]; Austin,  
 Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla,  
 Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael

(FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodríguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin

**Subject:** ACTIV Preclinical full working group

**When:** Wednesday, June 17, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

**Where:** <https://fnih.zoom.us> (b) (6)

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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**From:** Culp, Michelle (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4E38FA37E0424217AA0A283CBA9E5098-MCULP]  
**Sent:** 5/21/2020 9:58:09 PM  
**To:** Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]  
**Subject:** RE: Slides for ACTIV TX-Clinical Working Group Meeting #7

Yes and yes.

Let's just do a Skype call.

**From:** Gadbois, Ellen (NIH/OD) [E] <(b) (6)>  
**Sent:** Thursday, May 21, 2020 5:55 PM  
**To:** Culp, Michelle (NIH/OD) [E] <(b) (6)>  
**Subject:** RE: Slides for ACTIV TX-Clinical Working Group Meeting #7

Can we chat around 8:30 tomorrow a.m.? And I think we should send LT some kind of short alert tomorrow afternoon about some directives that may not be met cause ICs are doing their own thing anyway, unless they want to intervene with a strong directive. Personally I think this partnership should readjust to go wherever it looks like it can be most helpful and try not to bring sailed ships back, but I tend to be pessimistic about success of central control.

**From:** Culp, Michelle (NIH/OD) [E] <(b) (6)>  
**Sent:** Thursday, May 21, 2020 4:24 PM  
**To:** Gadbois, Ellen (NIH/OD) [E] <(b) (6)>  
**Subject:** RE: Slides for ACTIV TX-Clinical Working Group Meeting #7

No, so thanks for sending. I will request Stacey and Mike to add me to the Therapeutics Clinical and Vaccine WG calls. Do you want to chat this evening or tomorrow morning?

**From:** Gadbois, Ellen (NIH/OD) [E] <(b) (6)>  
**Sent:** Thursday, May 21, 2020 4:01 PM  
**To:** Culp, Michelle (NIH/OD) [E] <(b) (6)>  
**Subject:** FW: Slides for ACTIV TX-Clinical Working Group Meeting #7

Did you get this in time to join today? I did. You should try to follow this group. They mostly talked about their plans for a master protocol for the mAbs and I'm sure you would get more out of the details. But I have some observations (not urgent to discuss).

**From:** Adam, Stacey (FNIH) [T] <(b) (6)>  
**Sent:** Thursday, May 21, 2020 12:44 PM  
**To:** Bozzette, Sam (NIH/NCATS) [E] <(b) (6)> Butterson, Joan <joan (b) (6)> De Claro, R. Angelo (FDA/CDER) <(b) (6)> Draghia-Akli, Ruxandra <(b) (6)> Eisner, Mark <(b) (6)> Gottesdiener, Keith <(b) (6)> Hughes, Eric <(b) (6)> Judy Currier <(b) (6)> Kim, Elizabeth <(b) (6)> LaVange, Lisa <(b) (6)> Levy, Elliot <(b) (6)> Mellors, John W <(b) (6)> Menon, Sandeep <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Patel, Naimish <(b) (6)> Peppercorn, Amanda <(b) (6)> Poole, Mike <(b) (6)> Proschan, Michael (NIH/NIAID) [E] <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Shen, Yuan Li (FDA/CDER) <(b) (6)> Stein, Peter (FDA/CDER) <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Buchman, Tim (OS/ASPR/BARDA) (CTR) <(b) (6)> Collins, Sylvia (FDA/CDER) <(b) (6)> Amanda Peppercorn <(b) (6)> Garner, Carl

(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] < (b) (6) Koroshetz, Walter (NIH/NINDS)  
 [E] < (b) (6) Burgess, Timothy < (b) (6) Reineck, Lora (NIH/NHLBI) [E]  
 < (b) (6) Aggarwal, Neil (NIH/NHLBI) [E] < (b) (6) Rosenberg, Yves (NIH/NHLBI) [E]  
 < (b) (6) Brown, Jeremy (NIH/NINDS) [E] < (b) (6) Gadbois, Ellen (NIH/OD) [E]  
 < (b) (6)  
**Cc:** Colvis, Christine (NIH/NCATS) [E] < (b) (6) Desrosiers, Betsy (b) (6)  
 Jansen, Kathrin < (b) (6) Kurilla, Michael (NIH/NCATS) [E] < (b) (6) Lowy,  
 Douglas (NCI) < (b) (6) Young, John < (b) (6) Biggs, Mary < (b) (6)  
 Butcher, Tina (b) (6) Demarcus < (b) (6) Macone, Erin  
 < (b) (6) Melencio, Cheryl (FNIH) [T] < (b) (6) Salathin, Carla  
 < (b) (6) Tountas, Karen (FNIH) [T] < (b) (6) rg>, Menetski, Joseph (FNIH) [T]  
 < (b) (6) James, Stephanie (FNIH) [T] < (b) (6) Wachtel, Jonathan < (b) (6)  
 Tolman, Brett < (b) (6) Alvarez, Rosa < (b) (6) Gonzalez, Nina  
 < (b) (6) Dana Carluccio < (b) (6) Rose Li Central Account  
 < (b) (6) Anderson, Margaret < (b) (6) Lucas Sma Idon  
 (b) (6) Stratton, Benjamin < (b) (6)  
 (b) (6) Mollica, Linda /US < (b) (6) Qashu, Felicia (NIH/OD) [E]  
 < (b) (6) Patterson, Amy (NIH/NHLBI) [E] < (b) (6) Goff, David (NIH/NHLBI) [E]  
 < (b) (6) Rubin, Daniel B. (FDA/CDER) < (b) (6)  
**Subject:** Slides for ACTIV TX-Clinical Working Group Meeting #7

Dear ACTIV TX-Clinical WG,

Looking forward to seeing you all soon at the meeting Please find attached the slides for the meeting.

Thanks,  
Stacey

Stacey J. Adam, PhD  
 Director, Cancer  
 Research Partnerships  
 Direct: (b) (6) Mobile: (b) (6)

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 US (San Jose)  
 Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://fnih.zoom.us/j/9181234567> (b) (6)

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**From:** Freire, Maria (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8598D551D1D3455EAF14854C83F41D84-FREIREMC]  
**Sent:** 5/29/2020 10:06:43 PM  
**To:** Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]  
**Subject:** Re: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Francis - have you had a chance to chat with Janet to coordinate messages? She is critical - in her low-key way, she is able to carry a huge part of the load. Moncef knows she has a rock-solid reputation with industry folks. And, of course, she was the one who asked for the money. M.

On May 29, 2020, at 5:59 PM, Collins, Francis (NIH/OD) [E] < (b) (6) > wrote:

Hi all,

I have received information from Amy Patterson about the anticoagulant trial, and I'd like to have that incorporated into the slide set that Deloitte is currently working on. Attached is the document from Amy. I have highlighted the main points that I would want to have included in the slides, trying if possible to mirror the same features that are going to be included in the description of the immunomodulator study.

See what you think. I stand ready to look at ppts anytime this evening.

One question about the immunomodulator trial that I noticed in Moncef's note – has FDA agreed with the plan to move straight into phase 3 from a safety and efficacy standpoint?

Thanks, Francis

**From:** Wholley, David (FNIH) [T] < (b) (6) >  
**Sent:** Friday, May 29, 2020 1:59 PM  
**To:** Collins, Francis (NIH/OD) [E] < (b) (6) >  
**Cc:** Adam, Stacey (FNIH) [T] < (b) (6) > Freire, Maria (FNIH) [T] < (b) (6) > Gonzalez, Nina < (b) (6) > Parker, Ashley (NIH/OD) [E] < (b) (6) >  
**Subject:** Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Francis:

Here's the outline of the slides I am asking Deloitte to work to put together with key messages. I don't know if you or Ashley have a good version of slide #1, it is more of an OWS slide than an ACTIV one. I also don't know what input NHLBI wants to provide; I took the liberty of naming the anticoag MP as "ACTIV-4" in the interest of teaming up on a commonly branded strategy, hope that is OK. I am providing this to Deloitte now so they can get going on starting the slides, but please feel free to highlight maybe in red any wording you want changed or additions you would add in the meantime, and copy all on the reply.

- Maybe a diagram slide just reminding Moncef that OWS/Therapeutics and ACTIV are working together
- OWS/ACTIV Therapeutics has been taking a *portfolio* approach to addressing the dramatic health and economic challenges posed by the pandemic, with harmonized efforts that address both disease etiology and symptomology.
  - ACTIV Baricitinib (ACTT2, sponsored by NIAID) – in progress
  - ACTIV hiVIG (sponsored by NIAID) - in progress

- ACTIV-1 – Inpatient Master Protocol of 3 host-targeted immune modulators (using CRO) – (Phase III) – ready to launch late June
- ACTIV-2\* – Neutralizing Monoclonal Antibodies Outpatient Master Protocol (using NIAID ACTG Network + CRO) – (Phase II/III) – projected launch June
- ACTIV-3\* – Neutralizing Monoclonal Antibodies Inpatient Master Protocol (NIAID INSIGHT Network + NHLBI PETAL Network + CRO) – (Phase II/III) – projected launch July
- ACTIV-4 – Inpatient Master Protocols of 3+ Anticoagulant Therapies, and eventually, Anticoagulant+Immune Modulator Combinations (NHLBI-NINDS “Master” Network) – (Phase .I/III) – projected launch late June
- ACTIV-5 – De Novo Master Protocol Structure to test promising agents not effectively evaluated elsewhere (e.g., antivirals) – similar design to the mAb protocols, networks/sites/agents in discussions now – projected launch August (*if needed; i.e. if agents are not incorporated into mAb protocols*)
  - \* current priority
  - [for this slide I think you can use the Agent Prioritization Snapshot slide (#12) from May 20 ACTIV EC call as a base
- Prioritization Process (v 2.0) for ACTIV : (slide 14 from May 20 EC deck)
- Results of First Agent Prioritization Reviews (slide 13 from May 20 deck)
  - [Key Criteria for Scoring (slide 15 from 5/20) can go to backup
- Prioritization and Protocol Design: Who is Involved – two-box slide containing names and affiliations of those involved in the Prioritization and MP Subgroups (quality folks!)
- ACTIV-1 Protocol for immunomodulators
  - Agent prioritization included input from COVID R&D Leadership Consortium planned testing of 8-9 repurposed agents funded by industry (2 highest priority agents switched to ACTIV-1)
  - 3 agents chosen are well-established anti-inflammatories with solid rationale for MOA in COVID-19, not already being adequately tested elsewhere
  - All 3 either have initial Phase II data or are currently running company-sponsored Phase II trials = high POS
  - Phase III master protocol design for ACTIV-1 includes aggressive efficacy and futility assessments to allow for early stopping at 25%, 50%, and 75% accrual, in order to quickly drop agents not showing efficacy (like a Phase II/III progression design, but design was faster for quicker launch)
  - Companies have agreed to share data + common control arm+ common endpoints + DSMB = efficiency and ability to compare results across arms (this does not happen if companies test separately)
  - Protocol is 80% complete
    - Substantial input from 25+ industry, academic, and government experts, including FDA clinical and stats
      - Statisticians include some of the best in the world for master protocol design: Lisa LaVange (UNC), Karen Price (Lilly), Michael Proschan (NIAID), Sandeep Menon (Pfizer)
    - All three companies have written their sections of the protocols, which are being merged into the master design
  - Working with OWS/BARDA on choice of CRO to run the trial; (b) (5)
- “ACTIV 4” Protocol for anticoagulants
  - Need bullets from NHLBI on this. Should emphasize similar themes (robust choice of agents through ACTIV process, powered by NHLBI/NINDS “network of networks” with rapid contracting and startup practices, protocol being drafted in parallel (ACTIV WG review), inclusion of vital natural history disease/treatment data, cost and justification, etc.)
- Maybe a final slide summarizing the budget asks? Should it include preclinical or just the clinical stuff? And perhaps NIH (Ashley) should draft that one given the sensitivity around the numbers?

David Wholley  
 Senior Vice-President, Research Partnerships  
 Foundation for the National Institutes of Health



(b) (6)

[fnih.org](http://fnih.org)

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

*In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.*

<Responses to Qs re AC Clinical Trial Strategy 052920 final fsc.docx>

**From:** Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]  
**Sent:** 4/29/2020 10:35:13 PM  
**To:** Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; david.j. (b) (6)  
(b) (6) (b) (6) (b) (6) (b) (6)  
(b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];  
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];  
(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];  
(b) (6) ; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas /US [ (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]  
**CC:** Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [ (b) (6) Hughes, Enc [ (b) (6) Jansen, Kathrin (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [ (b) (6) Kim, Elizabeth [ (b) (6) Tolman, Brett [ (b) (6) Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [ (b) (6) Diamond, Michael [ (b) (6) Rose Li [ (b) (6) Dana Carluccio [dana. (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D  
[rmdaigle@tulane.edu]; Dave Frankowski (b) (6) Florence, Clint (NIH/NIAID) [E]  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Lowy, Douglas  
(NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]

**Subject:** ACTIV Preclinical working group (Friday meeting)

**Location:** <https://fnih.zoom.us/> (b) (6)

**Start:** 4/30/2020 3:00:00 PM

**End:** 4/30/2020 4:30:00 PM

**Show Time As:** Free

**Recurrence:** Weekly  
every Friday from 11:00 AM to 12:00 PM

**Required Attendees:** (b) (6) (b) (6) (b) (6) (b) (6)  
(b) (6) (b) (6) (b) (6) (b) (6)  
(b) (6) (b) (6) (b) (6) (b) (6)  
(b) (6) (b) (6) (b) (6) (b) (6)  
(b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];  
(b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas /US; Qashu, Felicia (NIH/OD) [E]  
**Optional Attendees:** Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine  
(NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas  
(NCI), Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T];  
James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachter, Jonathan; Prabhavathi  
Fernandes; Diamond, Michael; Rose Li, Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha  
(NIH/NCATS) [E]; Gonzalez, N na, Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D;  
Dave Frankowski; Florence, Clint (NIH/NIAID) [E]; Lowy, Douglas (NIH/NCI) [E]

Request to move due to holiday and extended by 30min

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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**Sent:** 6/7/2020 3:12:51 PM  
**To:** Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Smith, David [ (b) (6) Jens Lundgren (b) (6) Jim Neaton [ (b) (6) Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebcf48879f92169bd7644e29-Janet.Woodc]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]  
**CC:** Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Chen, Helen Q. [ (b) (6) Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Fleming, Amanda [ (b) (6) Lawlor, Ciarán [ (b) (6) Eric Hughes [ (b) (6) Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Moeller, Clemens [ (b) (6)  
**Subject:** OWS/ACTIV mAb Summit "Run-of-Show" Preparation Meeting  
**Attachments:** 09Jun2020\_Clinical summit\_vDraftv5.pptx

**Flag:** Follow up

Dear OWS/ACTIV mAb Summit Speakers and Team,

Please find attached the latest version of the presentations that we will go through in about 15 minutes.

Thanks,  
Stacey

Stacey J. Adam, PhD  
Director, Cancer  
Research Partnerships  
Foundation for the National Institutes of Health  
Direct: (b) (6) Mobile: (b) (6)  
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**From:** Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]  
**Sent:** 1/8/2021 7:44:55 PM  
**To:** Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]  
**CC:** Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]  
**Subject:** RE: Pandemic Preparedness proposal  
**Attachments:** Pandemic Preparedness preclinical budget estimate total 2021 Final Draft Just totals.xlsx; Preclinical therapeutic development overview 1 8 2021b.docx  
**Flag:** Follow up

Here s an updated excel file that shows the manufacture cost ramping up, but the total stays the same. I have also added a new version of the document, because the yearly numbers changed and that also needed to be updated for accuracy.

Best regards,  
Joe

**From:** Menetski, Joseph (FNIH) [T]  
**Sent:** Friday, January 8, 2021 2:03 PM  
**To:** Collins, Francis (NIH/OD) [E] < (b) (6) >  
**Cc:** Austin, Christopher (NIH/NCATS) [E] < (b) (6) > Freire, Maria (FNIH) [T] < (b) (6) > Wholley, David (FNIH) [T] < (b) (6) > Colvis, Christine (NIH/NCATS) [E] < (b) (6) >  
**Subject:** RE: Pandemic Preparedness proposal

Hi Francis,

I can make the ramp of manufacture cost, but the team felt there was a probability that there would be a need for drug scaling in the first year (so first year won't be zero). The work would be partially associated with potential drug combinations that are being already tested in vitro. I will get that to you in a few minutes.

Below are the NIH and BARDA representatives that were very active in the discussion yesterday. All of them have been sent the final version (including Gary Disbrow also) for their review and further discussion in their organizations.

Anderson, James (NIH/OD) [E]
Colvis, Christine (NIH/NCATS) [E]
Hall, Matthew (NIH/NCATS) [E]
Eakin, Ann (NIH/NIAID) [E]
Erbelding, Emily (NIH/NIAID) [E]
Read, Sarah (NIH/NIAID) [E]
Marks, Gilbert (OS/ASPR/BARDA) (CTR)
Erlandson, Karl (OS/ASPR/BARDA)
Chrzan, Kazimierz (OS/ASPR/BARDA) (CTR)
Austin, Christopher (NIH/NCATS) [E]



Best, Joe

**From:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Sent:** Friday, January 8, 2021 12:20 PM  
**To:** Menetski, Joseph (FNIH) [T] (b) (6)  
**Cc:** Austin, Christopher (NIH/NCATS) [E] (b) (6); Freire, Maria (FNIH) [T] (b) (6); Wholley, David (FNIH) [T] (b) (6); Colvis, Christine (NIH/NCATS) [E] (b) (6)  
**Subject:** RE: Pandemic Preparedness proposal

Hi Joe et al.,

This looks great -- nicely done, team!

One question -- in the budget table you have BARDA getting \$54M/year for manufacturing drug substance. I'm not clear what would be for the first couple of years. Shouldn't that start slow and then ramp up at the end when you need it? Can you see about rearranging some categories to make that fit?

Once I have that revised budget, I intend to run this past Janet Woodcock and Tony Fauci. Tony will want to know who from NIAID has had input, and who has reviewed the final version. What are the answers?

Thanks!

Francis

**From:** Menetski, Joseph (FNIH) [T] (b) (6)  
**Sent:** Friday, January 8, 2021 12:01 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Austin, Christopher (NIH/NCATS) [E] (b) (6); Freire, Maria (FNIH) [T] (b) (6); Wholley, David (FNIH) [T] (b) (6); Colvis, Christine (NIH/NCATS) [E] (b) (6)  
**Subject:** RE: Pandemic Preparedness proposal

Dear Francis,

Here is the next version of the proposal addressing your comments from last night. The narrative now focuses on antivirals for coronavirus early and then moves to a broader view. We have also split out the where we think the work and funds will need to go in the budget table.

Please let us know if this covers what you need in order to move this forward.

Best regards,  
Joe

**From:** Menetski, Joseph (FNIH) [T]  
**Sent:** Thursday, January 7, 2021 5:02 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Austin, Christopher (NIH/NCATS) [E] <(b) (6)>; Freire, Maria (FNIH) [T] <(b) (6)>; Wholley, David (FNIH) [T] <(b) (6)>; Menetski, Joseph (FNIH) [T] (b) (6); Colvis, Christine (NIH/NCATS) [E] <(b) (6)>  
**Subject:** Pandemic Preparedness proposal

Dear Francis,

Please find an updated version of the pandemic preparedness proposal. This has now had direct input from NIAID and BARDA, as well as the folks from earlier in the week. The list of folks is below.

The Narrative and budget files are attached. The budget currently contains a lot of detail, which I can easily remove if you wish, but the bottom line totals are pasted below.

Best regards,  
Joe

Overall Cost	
(b) (5)	
Overall total	
2021	
2022	
2023	
2024	
2025	

Anderson, James (NIH/OD) [E]  
Colvis, Christine (NIH/NCATS) [E]  
Hall, Matthew (NIH/NCATS) [E]  
Eakin, Ann (NIH/NIAID) [E]  
Erpelding, Emily (NIH/NIAID) [E]  
Read, Sarah (NIH/NIAID) [E]  
Marks, Gilbert (OS/ASPR/BARDA) (CTR)  
Er andson, Karl (OS/ASPR/BARDA)  
Chrzan, Kazimierz (OS/ASPR/BARDA) (CTR)

Joseph P. Menetski Ph.D.  
Associate Vice President, Research Partnerships  
Foundation for the National Institutes of Health  
(b) (6) [fnih.org](https://fnih.org)  
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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**From:** Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]  
**Sent:** 9/23/2020 2:14:19 PM  
**To:** Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]  
**CC:** Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]  
**Subject:** FW: Materials for September 23 ACTIV Partnership Leadership Team Teleconference TOMORROW MORNING

Hi Nancy – I do not know if you were able to be on today's ACTIV Leadership Team call, but please see the question from William Pao, who heads R&D at Roche, which I thought you might be best positioned to answer. Can you help me with a response? I am copying Francis Collins in case he has a perspective as well. Many thanks, David

**From:** Pao, William <(b) (6)>  
**Sent:** Wednesday, September 23, 2020 10:04 AM  
**To:** Wholley, David (FNIH) [T] <(b) (6)>  
**Subject:** RE: Materials for September 23 ACTIV Partnership Leadership Team Teleconference TOMORROW MORNING

Hi David,  
Very informative meeting as usual.  
I had a question maybe not related to ACTIV activities but to OWS or CDC. However, if addressed could help with recruitment on ACTIV studies.  
I noticed on this CDC link that the number of deaths related to COVID-19, pneumonia, or influenza for 2020 are nearly 300,000, while the number attributed to COVID-19 only are almost 200,000,  
<https://www.cdc.gov/nchs/nvss/vsrr/COVID19/index.htm>

To me, this suggests **many patients still are just not getting tested**. Is someone in the government addressing this? If addressed, maybe there'd be more patients to enroll in trials?

Best,  
William

**From:** Melencio, Cheryl (FNIH) [T] <(b) (6)> > On Behalf Of Wholley, David (FNIH) [T]  
**Sent:** Wednesday, September 23, 2020 2:35 AM  
**To:** Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Bancel, Stephane  
<(b) (6)> m>; Carter, Kara <(b) (6)> >; Cavaleri, Marco  
<(b) (6)> Cihlar, Tomas <(b) (6)> Collins, Francis (NIH/OD) [E]  
<(b) (6)> Corey, Larry <(b) (6)> >; Culp, Michelle (NIH/OD) [E] <(b) (6)> >;  
Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)> >; Dolsten, Mikael <(b) (6)> Erbeling,  
Emily (NIH/NIAID) [E] <(b) (6)> ; Erck, Stan <(b) (6)> >; Fauci, Anthony (NIH/NIAID) [E]  
<(b) (6)> ; Freire, Maria (FNIH) [T] <(b) (6)> ; Gadbois, Ellen (NIH/OD) [E]  
>; Gibbons, Gary (NIH/NHLBI) [E] <(b) (6)> Hudson, Thomas  
<(b) (6)> ; James, Stephanie (FNIH) [T] <(b) (6)> >; Johnson, Robert (OS/ASPR/BARDA)  
<(b) (6)> Kramer, Lynn <(b) (6)> >; Lane, Cliff (NIH/NIAID) [E] <(b) (6)>  
Lepore, John <(b) (6)> Marks, Peter (FDA/CBER) <(b) (6)> ; Marston, Hilary  
(NIH/NIAID) [E] <(b) (6)> ; Mascola, John (NIH/VRC) [E] <(b) (6)> >; Meeker, David  
<(b) (6)> >; Menetski, Joseph (FNIH) [T] <(b) (6)> >; Messonnier, Nancy  
(CDC/DDID/NCIRD/OD) <(b) (6)> Pandya, Hitesh <(b) (6)> ; Pangalos, Mene  
<(b) (6)> >; Pao, William <(b) (6)> <(b) (6)> Parker, Ashley (NIH/OD) [E]  
<(b) (6)> Paul, Steve <(b) (6)> Perlmutter, Roger <(b) (6)> >;  
Plenge, Robert <(b) (6)> Plump, Andy <(b) (6)> Rachel Ramoni

< (b) (6) Rasi, Guido < (b) (6) Reed, John (b) (6) >; Reese, David  
(b) (6) Rouse, Doris (b) (6) Santos, Michael (FNIH) [T] (b) (6) >; Skovronsky,  
Daniel (b) (6) >; Stein, Peter (FDA/CDER) (b) (6) Stoffels, Paul  
(b) (6) Tabak, Lawrence (NIH/OD) [E] (b) (6) ; Talley, Michael  
(b) (6) ; Tsai, John < (b) (6) ; Vessey, Rupert (b) (6) >; Virgin, Skip  
(b) (6) ; Wholley, David (FNIH) [T] (b) (6) Woodcock, Janet (FDA/CDER)  
(b) (6) ; Young, John <] (b) (6) >; Colvis, Christine (NIH/NCATS) [E]  
(b) (6) Desrosiers, Betsy < (b) (6) Eric Hughes  
< (b) (6) Jansen, Kathrin < (b) (6) Kurilla, Michael (NIH/NCATS) [E]  
(b) (6) >; Lowy, Douglas (NCI) < (b) (6) ; Read, Sarah (NIH/NIAID) [E] (b) (6)  
Young, John < (b) (6) (b) (6) Bugin, Kevin (FDA/CDER)  
(b) (6)

Cc: Anderson, James (NIH/OD) [E] (b) (6) i, Christopher (NIH/NCATS) [E]  
< (b) (6) >; Burklow, John (NIH/OD) [E] (b) (6) Carlucci, Dana  
(b) (6) ; Castillejos, Carlos < (b) (6) Culp, Michelle (NIH/OD) [E]  
(b) (6) FNIH Central Account (b) (6) ; Hallett, Adrienne (NIH/OD) [E]  
(b) (6) Myles, Renate (NIH/OD) [E] (b) (6) ; Parker, Ashley (NIH/OD) [E]  
< (b) (6) Gorman, Greta (FNIH) [T] (b) (6) >, Hallett, Adrienne (NIH/OD) [E]  
< (b) (6) Meltzer, Abbey (FNIH) [T] (b) (6) >; Wolinetz, Carrie (NIH/OD) [E]  
(b) (6) ; Adam, Stacey (FNIH) [T] (b) (6) Alvarez, Rosa Maria  
< (b) (6) Margaret Anderson < (b) (6) Appell, Evan < (b) (6)  
Chen, Helen Q. (b) (6) Elsaid, Olivia (b) (6) >; Gonzalez, Nina  
(b) (6) >; Hawk, Harrison (b) (6) >; Mendelson, Jesse (b) (6) ;  
Menetski, Joseph (FNIH) [T] (b) (6) >; Santos, Michael (FNIH) [T] (b) (6) Stratton, Benjamin  
< (b) (6) btolman < (b) (6) Tountas, Karen (FNIH) [T] (b) (6)  
Wachtel, Jonathan < (b) (6) Wholley, David (FNIH) [T] (b) (6) Melencio, Cheryl (FNIH)  
[T] (b) (6) >

**Subject:** Materials for September 23 ACTIV Partnership Leadership Team Teleconference TOMORROW MORNING

Dear Colleagues:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from **9:00 – 10:00 AM Eastern U.S. time tomorrow**, Wednesday September 23. I have also attached notes from our August 26 Leadership Team meeting as well as our last ACTIV EC meeting on September 9.

The Zoom meeting information is:

<https://fnih.zoom.us/>

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Meeting ID: (b) (6)

Passcode: (b) (6)

One tap mobile

(b) (6)

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US (Chicago)

Dial by your location

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US (San Jose)

US (San Jose)

US (Tacoma)

US (Houston)

Belgium

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United Kingdom

Meeting ID: (b) (6)

Passcode: (b) (6)

Find your local number: <https://fnih.zoom.us> (b) (6)

Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley  
Senior Vice-President, Research Partnerships  
Foundation for the National Institutes of Health  
(b) (6)  
fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

*In 2019, the FNHH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.*

**From:** Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]  
**Sent:** 5/11/2020 2:08:35 PM  
**To:** Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Dolsten, Mikael [ (b) (6) ]; Fauci, Anthony (NIH/NIAID) [E] [ (b) (6) ]; Gibbons, Gary (NIH/NHLBI) [E] [ (b) (6) ]; Pao, William [ (b) (6) ]; Stoffels, Paul [ (b) (6) ]; Woodcock, Janet (FDA/CDER) [ (b) (6) ]; Colvis, Christine (NIH/NCATS) [E] [ (b) (6) ]; Desrosiers, Betsy [ (b) (6) ]; Hughes, Eric [ (b) (6) ]; Jansen, Kathrin [ (b) (6) ]; Kurilla, Michael (NIH/NCATS) [E] [ (b) (6) ]; Lowy, Douglas (NCI) [ (b) (6) ]; Read, Sarah (NIH/NIAID) [E] [ (b) (6) ]; Young, John [ (b) (6) ]; Wholley, David (FNIH) [T] [ (b) (6) ]; Menetski, Joseph (FNIH) [T] [ (b) (6) ]; Adam, Stacey (FNIH) [T] [ (b) (6) ]; Tountas, Karen (FNIH) [T] [ (b) (6) ]; Santos, Michael (FNIH) [T] [ (b) (6) ]; Freire, Maria (FNIH) [T] [ (b) (6) ]; Tabak, Lawrence (NIH/OD) [E] [ (b) (6) ]; Lane, Cliff (NIH/NIAID) [E] [ (b) (6) ]; Parker, Ashley (NIH/OD) [E] [ (b) (6) ]; Anderson, James (NIH/OD) [E] [ (b) (6) ]; Austin, Christopher (NIH/NCATS) [E] [ (b) (6) ]; Wolinetz, Carrie (NIH/OD) [E] [ (b) (6) ]; Barasch, Kimberly (NIH/NIAID) [C] [ (b) (6) ]; Conrad, Patricia (NIH/NIAID) [E] [ (b) (6) ]; Dimishkov, Roxanne (NIH/NHLBI) [C] [ (b) (6) ]; McManus, Ayanna (NIH/OD) [E] [ (b) (6) ]; Protasiewicz, Ann [ann. (b) (6) ]; Thomas, Ashley (FDA/CDER) [ (b) (6) ]; Wood, Gretchen (NIH/OD) [E] [ (b) (6) ]; Zanelato, Ann [ (b) (6) ]; Zottoli, Jessica [ (b) (6) ]; Togashi, Mieko (NIH/NC) [E] [ (b) (6) ]; Sepulveda, Dorina (FNIH) [T] [ (b) (6) ]; Lagos, Enrique (NIH/NCATS) [E] [ (b) (6) ]; Simon, Dina (NIH/OD) [C] [ (b) (6) ]; Burrus-Shaw, Cyndi (NIH/OD) [E] [ (b) (6) ]; Hardesty, Rebecca (NIH/OD) [C] [ (b) (6) ]; Alvarez, Rosa [ (b) (6) ]; Anderson, Margaret [ (b) (6) ]; Elsaid, Olivia [ (b) (6) ]; Gonzalez, Nina [ (b) (6) ]; Kim, Elizabeth [ (b) (6) ]; Stratton, Ben [ (b) (6) ]; Tolman, Brett [ (b) (6) ]; Wachtel, Jonathan [ (b) (6) ];

**Subject:** ACTIV mtg with Exec Comm and WG co-chairs

**Location:** <https://fnih.zoom.us/> (b) (6)

**Start:** 5/13/2020 12:00:00 PM

**End:** 5/13/2020 1:00:00 PM

**Show Time As:** Busy

**Required Attendees:** Collins, Francis (NIH/OD) [E]; Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Pao, William; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Wholley, David (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Freire, Maria (FNIH) [T]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Wolinetz, Carrie (NIH/OD) [E]

**Optional Attendees:** Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Protasiewicz, Ann; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Zanelato, Ann; Zottoli, Jessica; Togashi, Mieko (NIH/NCI) [E]; Sepulveda, Donna (FNIH) [T]; Lagos, Enrique (NIH/NCATS) [E]; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Hardesty, Rebecca (NIH/OD) [C]; Alvarez, Rosa; Anderson, Margaret; Elsaid, Olivia; Gonzalez, Nina; Kim, Elizabeth; Stratton, Ben; Tolman, Brett; Wachtel, Jonathan

Cheryl Melencio is inviting you to a scheduled Zoom meeting.

**Join Zoom Meeting**

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JS (Germantown)

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US (Tacoma)

US (Houston)

US (San Jose)

US (San Jose)

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://fnlh.zoom.us>

(b) (6)

**To:** King, James (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce1f3853e43d4463a04f7d74992f96ac-James.King ]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Bascles, Lionel [ (b) (6) Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron\_cohen]; Corey, Larry [lcorey@fredhutch.org]; Desrosiers, Betsy [ (b) (6) Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickens]; Doroshov, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshov]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294c7bb99c10-goffdc]; Kurlla, Michael (NIH/NCATS) [E] [ (b) (6) Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Payton, Manizhe (NIH/NIAID) [E] [ (b) (6) Resnansky, Laura [ (b) (6) Srinivasan, Badhri [badhri. (b) (6) Wachtel, Jonathan [ (b) (6) ]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Vincent, Mike [ (b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]

**CC:** Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Jansen, Kathrin [ (b) (6) Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Saran (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [ (b) (6) Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc8d875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [ (b) (6) Carluccio, Dana [ (b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina [ (b) (6) Heaton, Penny [ (b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [ (b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [ (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin [ (b) (6) Minnich, Beth [ (b) (6) Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Stratton, Benjamin [ (b) (6) Tolman, Brett [ (b) (6) Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Jintanat Ananworanich [ (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Kenny, Dermot [ (b) (6) Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]; Garner, Carlos [ (b) (6) Hughes, Eric [ (b) (6) Hamilton, Nancy [ (b) (6)

**Attachments:** Clinical Trial Capacity Working Group Meeting Agenda 05192020.pdf

**Location:** <https://zoom.us/> (b) (6)

**Start:** 5/19/2020 1:00:00 PM

**End:** 5/19/2020 2:00:00 PM

**Show Time As:** Tentative

**Recurrence:** (none)

every Tuesday and Friday from 9:00 AM to 10:00 AM

**Required Attendees:** Vincent, Mike; Stein, Peter (FDA/CDER); Bascles, Lionel; Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manzine; Resnansky, Laura; Srinivasan, Badrin; Wachtel, Jonathan; Qashu, Felicia

**Optional Attendees:** Sizemore, Christine (NIH/FIC) [E]; Kenny, Dermot; Weinmann, Gail (NIH/NHLBI) [E]; Garner, Carlos; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathryn; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Carluccio, Dana; Cheryl (FNIH) Melencio [T] (b) (6); Francis Collins; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetsky, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E] (b) (6); Stratton, Benjamin; Tolman, Brett; Davey, Victoria; Jintanat Ananworanich

Dear Colleagues, We have an interesting agenda (attached) for this call and look forward to the discussion surrounding each topic! Best, Karen

#### ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards,  
Karen

Karen H. Tountas, PhD  
Scientific Program Manager  
Foundation for the National Institutes of Health

#### Join Zoom Meeting

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Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://zoom.us> (b) (6)

**From:** Gadbois, Ellen (N H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]  
**Sent:** 7/24/2020 6:20:42 PM  
**To:** Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]  
**Subject:** RE: Summary of the ACTIV Immune Modulator Prioritization Adjudication and Confidentiality Forms

Thanks Joe

**From:** Menetski, Joseph (FNIH) [T] <(b) (6)>  
**Sent:** Friday, July 24, 2020 1:26 PM  
**To:** Gadbois, Ellen (NIH/OD) [E] <(b) (6)>  
**Subject:** FW: Summary of the ACTIV Immune Modulator Prioritization Adjudication and Confidentiality Forms

Ellen,

An example of what is going out when we need agreements to review therapeutics.

Joe

**From:** Adam, Stacey (FNIH) [T] <(b) (6)>  
**Sent:** Friday, July 24, 2020 12:57 PM  
**To:** Chen, Helen Q. <(b) (6)>; Deye, Greg (NIH/NIAID) [E] <(b) (6)>; Fessel, Josh (NIH/NHLBI) [E] <(b) (6)>; Punturieri, Antonello (NIH/NHLBI) [E] <(b) (6)>; McNamara, James (NIH/NIAID) [E] <(b) (6)>; Wung, Peter /US <(b) (6)>; Vincent, Michael <(b) (6)>; Goff, David (NIH/NHLBI) [E] <(b) (6)>; Garner, Carl <(b) (6)>; Robien, Mark (NIH/NIAID) [E] <(b) (6)>; Togias, Alkis (NIH/NIAID) [E] <(b) (6)>; Patel, Naimish <(b) (6)>; Gottesdiener, Keith <(b) (6)>; Eric Hughes <(b) (6)>; Aggarwal, Neil (NIH/NHLBI) [E] <(b) (6)>; Levy, Elliot <(b) (6)>; Rosenberg, Yves (NIH/NHLBI) [E] <(b) (6)>; Buchman, Tim (OS/ASPR/BARDA) <(b) (6)>; (CTR) <(b) (6)>; Dana Carluccio <(b) (6)>; Rose Li Central Account <(b) (6)>; Read, Sarah (NIH/NIAID) [E] <(b) (6)>; Young, John <(b) (6)>; Colvis, Christine <(b) (6)>; (NIH/NCATS) [E] <(b) (6)>; Menetski, Joseph (FNIH) [T] <(b) (6)>; Alvarez, Rosa Maria <(b) (6)>

**Subject:** Summary of the ACTIV Immune Modulator Prioritization Adjudication and Confidentiality Forms

Dear Agent Prioritization Immune Modulator Subteam,

Please find attached the summary of our adjudication meeting on Wednesday. If you have any additions or amendments, please let us know.

In addition, based on our last cycle of reviews, the group expressed a desire to request more information for a few compounds that are requesting CDAs to release the data. In order to obtain this information, we will need to sign a CDA with this group to receive the information. Therefore, we will also need each of you (who is not a government employee) to sign a confidentiality agreement with us, so that we can then share the data with you.

Please find attached the template for the confidentiality agreements that we have been using for any of our ACTIV TX-Clinical WG members that needed to view confidential information. You will see that there are two versions of the confidentiality agreement.

- One version is for those individuals who are able to sign this type of agreement on your own behalf.
- One version is for those individuals whose institutions require that the institutional signatory sign on the individual's behalf.

We provide both options upfront as we may not which will apply to each of you.

Please review the confidentiality agreement and send back the signed copy as soon as you can. Once we have all of these signed and the information from the agent teams, we will circulate to the group for final review and decision on that agent. Please note, if you signed one of these for the Antiviral group, it will apply this one as well and you do not need to sign another.

Please return your signed agreement to Helen or myself as soon as you can. If you have any questions, do not hesitate to reach out.

Thanks,  
Stacey

**Stacey J. Adam, PhD**  
Director, Cancer  
Research Partnerships  
**Foundation for the National Institutes of Health**  
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(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];  
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**CC:** Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [ (b) (6) Hughes, Eric [ (b) (6) Jansen, Kathryn [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [ (b) (6) Kim, Elizabeth [ (b) (6) Tolman, Brett [ (b) (6) Wachtel, Jonathan [ (b) (6) Prabhavathi Fernandes [ (b) (6) Diamond, Michael [ (b) (6) Rose Li [ (b) (6) Dana Carluccio [ (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [ (b) (6)



**Subject:** COVID Preclinical working group (meeting # 1)  
**Attachments:** PRECLINICAL Agenda, Questions and Bios for Therapeutics- Preclinical Working Group FNIH 0414 vF5.pdf;  
PRECLINICAL - Agenda and questions for first working group meeting 4 14 2020\_VF.docx  
**Location:** <https://zoom.us/> (b) (6)

**Start:** 4/14/2020 6:00:00 PM  
**End:** 4/14/2020 7:30:00 PM  
**Show Time As:** Tentative

**Required Attendees:** (b) (6) (b) (6) : (b) (6) (b) (6)  
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(b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];  
(b) (6) Adams, Peter (OS/ASPR/BARDA)

**Optional Attendees:** Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachter, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li, Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D

Update: 4/14/2020 1:14; Added meeting materials

Dear preclinical working group members,

Thank you for agreeing to participate in this working group to help guide the COVID partnership effort. We are looking forward to working with you. We understand that time is of the essence and that many of you are occupied with other activities that address the COVID-19 pandemic. However, we ask for your flexibility and patience as we begin to schedule these meetings. We will do our best to ensure that all can attend and participate.

We will be sending additional materials in the next day or so for you to prepare for this meeting. This will let us get to the important discussions and decisions that we need to make to move the process forward rapidly.

Thank you again for your willingness to participate.

Sincerely,

Joe Menetski, for COVID preclinical working group

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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(b) (6) (b) (6) (b) (6) Erbelding, Emily (NIH/NIAID) [E] [ (b) (6)  
(b) (6) (b) (6) (b) (6) Gruber, Marion (FDA/CBER)  
(b) (6) (b) (6) (b) (6) Hamilton, Holli (OS/ASPR/BARDA)  
(b) (6) (b) (6) (b) (6) Ledgerwood, Julie (NIH/NIAID)  
[E] [ (b) (6) (b) (6) (b) (6) Lowy, Douglas (NIH/NCI)  
[E] [ (b) (6) Marks, Peter (FDA/CBER) [ (b) (6) Marovich, Mary (NIH/NIAID) [E]  
(b) (6) Mascola, John (NIH/VRC) [E] [ (b) (6) Nelson Michael  
(b) (6) Kathleen Neuzil [ (b) (6) Offit, Paul [ (b) (6)  
Merlin Robb [ (b) (6) (b) (6) Wholley, David (FNIH) [T] [ (b) (6)  
Melencio, Cheryl (FNIH) [T] [ (b) (6) Laurent Humeau [ (b) (6) Schrag, Stephanie  
(CDC/DDID/NCIRD/DBD) [ (b) (6) Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) [ (b) (6) Parker,  
Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wachtel, Jonathan  
[ (b) (6) Hotez, Peter Jay [ (b) (6) [ (b) (6) Tal Zaks  
[ (b) (6) (b) (6) Greg Glenn [ (b) (6)  
(b) (6) Jacqueline Miller [ (b) (6) François P Roman  
(b) (6) Culp, Michelle (NIH/OD) [E] [ (b) (6) Martin, Stacey  
(CDC/DDID/NCEZID/DVBD) [ (b) (6) McNamara, Lucy Alexandra (CDC/DDID/NCIRD/DBD) [ (b) (6)  
Goldstein, Jason (CDC/DDID/NCEZID/DSR) [ (b) (6) Schully, Sheri (NIH/OD) [E] [ (b) (6) ]; Sotir,  
Mark (CDC/DDID/NCIRD/DVD) [ (b) (6) ]; Arvin, Ann [ (b) (6) Hepburn, Matt (HHS/IOS)  
[ (b) (6) Najaf Shah [ (b) (6) ]; Michael Choy [ (b) (6) Gorman,  
Richard (OS/ASPR/BARDA) [ (b) (6) Johnson, Robert (OS/ASPR/BARDA)  
[ (b) (6) Buchbinder, Susan (DPH) [ (b) (6) mmdavis  
[ (b) (6) (b) (6) Haynes, Barton [ (b) (6)  
(b) (6) Messonnier, Nancy (CDC/DDID/NCIRD/OD) [ (b) (6) (b) (6) Seals,  
Jonathan (OS/ASPR/BARDA) [ (b) (6) ]; Tartaglia, Jim /US [Jim. (b) (6)  
(b) (6) Rotrosen, Daniel (NIH/NIAID) [E] [ (b) (6) .gov]; Togias, Alkis  
(NIH/NIAID) [E] [ (b) (6) (b) (6) (b) (6)  
(b) (6) Gebro, Kelly (NIH/OD) [G] [/o=ExchangeLabs/ou=Exchange Administrative Group  
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**CC:** btolman [ (b) (6) (b) (6) (b) (6) (b) (6)  
(b) (6) (b) (6) (b) (6) (b) (6) Johnson, Maureen (NIH/NCI) [E]  
[ (b) (6) Kozlowski, Mary (NIH/NCI) [C] [ (b) (6) Austin, Sarah (NIH/NIAID) [E]  
[ (b) (6) Soriano Osejo, Douglas [ (b) (6) Sitar, Sandra (NIH/VRC) [C]  
[ (b) (6) Tong, Tina (NIH/NIAID) [E] [tina. (b) (6) Kurilla, Michael (NIH/NCATS) [E]  
[ (b) (6) Tountas, Karen (FNIH) [T] [ (b) (6) Desrosiers, Elizabeth A.  
[ (b) (6) Isabel Ramsey [ (b) (6) Sridhar, Saranya /US  
[ (b) (6) Cheryl Keech [ (b) (6) Sadoff, Jerald [JRDUS] [ (b) (6)  
Michael, Nelson [ (b) (6) Marston, Hilary (NIH/NIAID) [E] [ (b) (6)  
(b) (6) (b) (6) Shannon Devine [ (b) (6) Long, Jemma  
(NIH/NIAID) [E] [ (b) (6) Antonio Lanzavecchia [ (b) (6) Kate Broderick  
[ (b) (6) Jean Boyer [ (b) (6) Mammen Mammen  
[ (b) (6) Brian Rosen [ (b) (6) Kayvon Modjarrad  
[ (b) (6)

**Subject:** ACTIV Vaccines Clinical Trials Sub-Group Meeting  
**Location:** <https://fnih.zoom.us/> (b) (6)  
**Start:** 1/15/2021 7:00:00 PM  
**End:** 1/15/2021 8:00:00 PM  
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**Required Attendees:** (b) (6) (b) (6) (b) (6) Cohen, Myron; (b) (6)  
 Erbeling, Emily (NIH/NIAID) [E]; pgil (b) (6) ; (b) (6) Gruber,  
 Marion (FDA/CBER); (b) (6) Hamilton, Holli (OS/ASPR/BARDA);  
 (b) (6) Ledgerwood, Julie (NIH/NIAID) [E];  
 (b) (6) Lowy, Douglas (NIH/NCI) [E]; Marks, Peter (FDA/CBER);  
 Marovich, Mary (NIH/NIAID) [E], Mascola, John (NIH/VRC) [E]; Nelson Michael; (b) (6)  
 Kathleen Neuzil; Offit, Paul; Merin Robb; (b) (6) Wholley, David (FNIH) [T]; Melencio,  
 Cheryl (FNIH) [T]; Laurent Humeau; Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R.  
 (CDC/DDID/NCIRD/DBD); Parker, Ashley (NIH/OD) [E]; Wachtel, Jonathan; Hotez, Peter Jay;  
 (b) (6) Tal Zaks; (b) (6) Greg Glenn;  
 (b) (6) Gebo, Kelly (NIH/OD) [G]; Jacqueline Miller; François P Roman; Culp, Michelle  
 (NIH/OD) [E]; Martin, Stacey (CDC/DDID/NCEZID/DVBD); McNamara, Lucy Alexandra (CDC/DDID/NCIRD/DBD);  
 Goldstein, Jason (CDC/DDID/NCEZID/DSR); Schully, Sheri (NIH/OD) [E]; Sotir, Mark (CDC/DDID/NCIRD/DVD); Arvin,  
 Ann; Hepburn Matt (HHS/IOS); Najaf Shah; Michael Choy; Gorman, Richard (OS/ASPR/BARDA); Johnson, Robert  
 (OS/ASPR/BARDA); Buchbinder, Susan (DPH); (b) (6) (b) (6) Haynes, Barton;  
 (b) (6) Messonnier, Nancy (CDC/DDID/NCIRD/OD); (b) (6) Seals, Jonathan  
 (OS/ASPR/BARDA); Tartaglia, Jim /US; (b) (6) Rotrosen, Danie (NIH/NIAID) [E]; Tog as,  
 Alkis (NIH/NIAID) [E]; (b) (6) (b) (6)  
**Optional Attendees:** Tolman, Brett; (b) (6) (b) (6) (b) (6)  
 Jessica. (b) (6) (b) (6) Johnson, Maureen (NIH/NCI) [E]; Kozlowski, Mary (NIH/NCI)  
 [C]; Austin, Sarah (NIH/NIAID) [E]; Soriano Osejo, Douglas; Sitar, Sandra (NIH/VRC) [C]; Tong, Tina (NIH/NIAID) [E];  
 Kurilla, Michael (NIH/NCATS) [E]; Tountas, Karen (FNIH) [T]; Desrosiers, Elizabeth A.; Isabel Ramsey; Sridhar, Saranya  
 /US; Brian Rosen; Cheryl Keech; Sadoff, Jerald [JRDUS]; Michael, Nelson; Kayvon Modjarrad; Marston, Hilary  
 (NIH/NIAID) [E]; (b) (6) (b) (6) Shannon Devine; Long, Jemma (NIH/NIAID)  
 [E]; Antonio Lanzavecchia; Kate Broderick; Jean Boyer; Mammen Mammen

**Topic:** ACTIV Vaccines Clinical Trials Sub-Group Meeting  
**Time:** Jan 15, 2021 02:00 PM Eastern Time (US and Canada)

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**Sent:** 1/22/2021 1:30:21 PM  
**To:** Young, John [ (b) (6) Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]  
**CC:** Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan\_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [ (b) (6) Gottesdiener, Keith [ (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [ (b) (6) LaVange, Lisa [ (b) (6) Levy, Elliot [ (b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [naimish.patel@sanofi.com]; Peppercorn, Amanda [ (b) (6) Poole, Mike [ (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia Colli]; Amanda Peppercorn [ (b) (6) Garner, Carl [ (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [ (b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative

Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Philips, L Revell CIV DTRA RD (USA) | (b) (6) Petrovick, Martha - 0449 - MITLL | (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, H.lary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Wung, Peter /US | (b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) | (b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) | (b) (6) Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact\_f12]; Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; Lerner, Andrea (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53254f4fb04e4bcbabe37940b4b41887-fennellyam]; Embry, Aran (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]

**Subject:** RE: Master Protocol Development and Agent Prioritization Manuscripts for ACTIV TX-C inical Comment

Small point.

We classified one group as "symptomatic/supportive". Not sure how that is perceived. In my area symptomatic treatment makes you feel better or function better, but has no effect on disease biology- like Tylenol for cold symptoms. I think everything we looked at was actually disease-modifying-- aimed at preventing tissue injury, so "organ supportive" or "organ support"

walter

**From:** Young, John < (b) (6) >  
**Sent:** Friday, January 22, 2021 7:33 AM  
**To:** Adam, Stacey (FNIH) [T] < (b) (6) >  
**Cc:** Bozzette, Sam (NIH/NCATS) [E] < (b) (6) > Butterson, Joan < (b) (6) > De Claro, R. Angelo (FDA/CDER) < (b) (6) > Draghia-Akli, Ruxandra < (b) (6) > Gottesdiener, Keith < (b) (6) > Eric Hughes < (b) (6) > Judy Currier < (b) (6) > Kim, Elizabeth < (b) (6) > LaVange, Lisa < (b) (6) > Levy, Elliot < (b) (6) > Mellors, John W < (b) (6) > Menon, Sandeep < (b) (6) > Parker, Ashley (NIH/OD) [E] < (b) (6) > Patel, Naimish < (b) (6) > Peppercorn, Amanda < (b) (6) > Poole, Mike < (b) (6) > Proschan, Michael (NIH/NIAID) [E] < (b) (6) > Read, Sarah (NIH/NIAID) [E] < (b) (6) > Santos, Michael (FNIH) [T] < (b) (6) > Shen, Yuan Li (FDA/CDER) < (b) (6) > Stein, Peter (FDA/CDER) < (b) (6) > Wholley, David (FNIH) [T] < (b) (6) > Buchman, Tim (OS/ASPR/BARDA) (CTR) < (b) (6) > Collins, Sylva (FDA/CDER) < (b) (6) > Amanda Peppercorn



< (b) (6) Garner, Carl < (b) (6) Higgs, Elizabeth (NIH/NIAID) [E]  
 < (b) (6) Koroshetz, Walter (NIH/NINDS) [E] < (b) (6) Timothy Burgess  
 < (b) (6) Reineck, Lora (NIH/NHLBI) [E] < (b) (6) Aggarwal, Neil (NIH/NHLBI) [E]  
 < (b) (6) Rosenberg, Yves (NIH/NHLBI) [E] < (b) (6) Goff, David (NIH/NHLBI) [E]  
 < (b) (6) Brown, Jeremy (NIH/NINDS) [E] < (b) (6) Gadbois, Ellen (NIH/OD) [E]  
 < (b) (6) Culp, Michelle (NIH/OD) [E] < (b) (6) Jacqueline Kirchner  
 < (b) (6) Beigel, John (NIH) [E] < (b) (6) Phillips, L Revell CIV DTRA  
 RD (USA) < (b) (6) Petrovick, Martha - 0449 - MITLL < (b) (6)  
 (b) (6) Sizemore, Christine (NIH/FIC) [E] < (b) (6) Colvis, Christine  
 (NIH/NCATS) [E] < (b) (6) Menetski, Joseph (FNIH) [T] < (b) (6) Patterson, Amy  
 (NIH/NHLBI) [E] < (b) (6) Rubin, Daniel B. (FDA/CDER) < (b) (6) Marston, Hilary  
 (NIH/NIAID) [E] < (b) (6) Chen, Helen < (b) (6) Wung, Peter /US  
 < (b) (6) Hoots, W Keith (NIH/NHLBI) [E] < (b) (6) Kindzelski, Andrei (NIH/NHLBI)  
 [E] < (b) (6) Hone, David M (Dave) CIV DTRA J9 (USA) < (b) (6) Reisler,  
 Ronald B CTR USARMY DOD JPEO CBRND (USA) < (b) (6) Sorosa, Alex < (b) (6)  
 Lumsden, Joanne (NIH/NCATS) [C] < (b) (6) Lerner, Andrea (NIH/NIAID) [E]  
 < (b) (6) Embry, Alan (NIH/NIAID) [E] < (b) (6)

**Subject:** Re: Master Protocol Development and Agent Prioritization Manuscripts for ACTIV TX-Clinical Comment

Hi Stacey

Manuscript reads well and is in excellent shape. I have no further comments.

Best regards

John

On Thu, Jan 21, 2021 at 4:57 AM Adam, Stacey (FNIH) [T] < (b) (6) wrote:

**CONFIDENTIAL – DO NOT SHARE BEYOND GROUP**

Dear ACTIV TX-Clinical WG,

As discussed on last week's call, I am now distributing the current 90% finalized drafts of the Master Protocol Development and Agent Prioritization manuscripts for this group's review and comment. Please find the manuscripts at these links:

Agent Prioritization:

[https://docs.google.com/document/d/1w\\_wKs1\\_bX2E\\_pdfmcXvz-0qW2cMey0w0RqUu1wMU2vE/edit](https://docs.google.com/document/d/1w_wKs1_bX2E_pdfmcXvz-0qW2cMey0w0RqUu1wMU2vE/edit)

Master Protocol Development:

[https://docs.google.com/document/d/1nIZT4\\_rPR6v1lbtCEdnE2hUumo6BsiQu85dW7Pd0xGU/edit](https://docs.google.com/document/d/1nIZT4_rPR6v1lbtCEdnE2hUumo6BsiQu85dW7Pd0xGU/edit)

We would ask that the team members here review the document to ensure that you feel it accurately reflects the process and efforts of this WG. ***We would ask that the group focus on any major comments that you feel are***

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***“critical” to the manuscript. We would ask that you not wordsmith or refine for style at this point, as each of these documents have been through about ~10 of your colleagues for drafting, review, and refinement.***

If you do have suggestions, please follow the instructions at the top of the Google document in green to turn on suggestions in the document before you edit. **If you do choose to comment, please ensure that you have all suggestions returned by a week from today on Wednesday, January 27<sup>th</sup> at 5pm ET.**

Finally, we would ask that you do not share these manuscripts with anyone outside of this distribution list at this time. They are still in draft phase and confidential, so we do not wish to hurt our chance of publication by having them made public to early and in their unfinished form.

Thank you in advance for your assistance with this effort.

Kind regards,

Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

Direct: (b) (6) | Mobile: (b) (6)

fnihi.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



--  
**John A.T. Young, PhD**

VP and Global Head Infectious Diseases  
Roche Pharma Research & Early Development  
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Mail to

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**Sent:** 8/26/2020 2:32:55 AM  
**To:** Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]  
**CC:** Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]  
**Subject:** Re: Materials for August 26 ACTIV Partnership Leadership Team Teleconference  
**Attachments:** 8.26 ACTIV Leadership Team Meeting 20200825 vFinal.pdf; 2020-07-29\_ACTIV\_Leadership\_Team\_Meeting\_Summary final.pdf; 2020-08-14\_Executive\_Committee\_Meeting\_Summary vFinal.pdf

Hi Francis,

To ensure the ICDs receive the information for the ACTIV LT meeting tomorrow – would you like to forward the following to the ICD only list. Below is a draft note for consideration.

To: ICD-ONLY-L@LIST.NIH.GOV

Cc: Wholley, David (FNIH) [T] < (b) (6) > Melencio, Cheryl (FNIH) [T] < (b) (6) >

Dear Colleagues,

As discussed during our conference call this afternoon, ICDs (**principals only please; no surrogates or additional staff**) are invited to join the virtual ACTIV leadership team meeting tomorrow August 26, 3:00-4:00pm. Please see the attached materials and link below. If you are able to join please ensure David Wholley and Cheryl Melencio know you are available to attend and please remain in “listen-only” mode during the meeting.

Thank you,  
Francis

**From:** Melencio, Cheryl (FNIH) [T] < (b) (6) > **On Behalf Of** Wholley, David (FNIH) [T]  
**Sent:** Tuesday, August 25, 2020 9:47 PM  
**To:** Austin, Christopher (NIH/NCATS) [E] < (b) (6) > Bancel, Stephane  
< (b) (6) > Carter, Kara < (b) (6) > Cavaleri, Marco  
< (b) (6) > Cihlar, Tomas < (b) (6) > Collins, Francis (NIH/OD) [E]  
< (b) (6) > Corey, Larry < (b) (6) > Culp, Michelle (NIH/OD) [E] < (b) (6) >  
Disbrow, Gary (OS/ASPR/BARDA) < (b) (6) > Dolsten, Mikael < (b) (6) > Erbeling,  
Emily (NIH/NIAID) [E] < (b) (6) > Erck, Stan < (b) (6) > Fauci, Anthony (NIH/NIAID) [E]  
< (b) (6) > Freire, Maria (FNIH) [T] < (b) (6) > Gadbois, Ellen (NIH/OD) [E]  
< (b) (6) > Gibbons, Gary (NIH/NHLBI) [E] < (b) (6) > Hudson, Thomas  
< (b) (6) > James, Stephanie (FNIH) [T] < (b) (6) > Johnson, Robert (OS/ASPR/BARDA)  
< (b) (6) > Kramer, Lynn < (b) (6) > Lane, Cliff (NIH/NIAID) [E] < (b) (6) >  
Lepore, John < (b) (6) > Marks, Peter (FDA/CBER) < (b) (6) > Marston, Hilary  
(NIH/NIAID) [E] < (b) (6) > Mascola, John (NIH/VRC) [E] < (b) (6) > Meeker, David  
< (b) (6) > Menetski, Joseph (FNIH) [T] < (b) (6) > Messonnier, Nancy  
(CDC/DDID/NCIRD/OD) < (b) (6) > Pandya, Hitesh < (b) (6) > Pangalos, Mene  
< (b) (6) > Pao, William <william. > (b) (6) > Parker, Ashley (NIH/OD) [E]  
< (b) (6) > Paul, Steve < (b) (6) > Perlmutter, Roger < (b) (6) >  
Plenge, Robert < (b) (6) > Plump, Andy < (b) (6) > Rachel Ramoni  
< (b) (6) > Rasi, Guido < (b) (6) > Reed, John < (b) (6) > Reese, David  
< (b) (6) > Rouse, Doris < (b) (6) > Santos, Michael (FNIH) [T] < (b) (6) > Skovronsky,

Daniel < (b) (6) Stein, Peter (FDA/CDER) < (b) (6) Stoffels, Paul  
 < (b) (6) Tabak, Lawrence (NIH/OD) [E] < (b) (6) Talley, Michael  
 < (b) (6) Tsai, John < (b) (6) Vessey, Rupert < (b) (6) Virgin, Skip  
 < (b) (6) Wholley, David (FNIH) [T] < (b) (6) Woodcock, Janet (FDA/CDER)  
 < (b) (6) Young, John < (b) (6) Colvis, Christine (NIH/NCATS) [E]  
 < (b) (6) Desrosiers, Betsy < (b) (6) Eric Hughes  
 < (b) (6) Jansen, Kathrin < (b) (6) Kurilla, Michael (NIH/NCATS) [E]  
 < (b) (6) Lowy, Douglas (NCI) < (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6)  
 Young, John < (b) (6)  
 Cc: Adam, Stacey (FNIH) [T] < (b) (6) Alvarez, Rosa < (b) (6) Anderson, Margaret  
 < (b) (6) Chen, Helen < (b) (6) Elsaid, Olivia < (b) (6)  
 Gonzalez, Nina < (b) (6) Hawk, Harrison < (b) (6) Menetsky, Joseph (FNIH) [T]  
 < (b) (6) Santos, Michael (FNIH) [T] < (b) (6) Stratton, Benjamin < (b) (6)  
 btolman < (b) (6) Tountas, Karen (FNIH) [T] < (b) (6) Wachtel, Jonathan  
 < (b) (6) Wholley, David (FNIH) [T] < (b) (6) Anderson, James (NIH/OD) [E]  
 < (b) (6) Austin, Christopher (NIH/NCATS) [E] < aust (b) (6) Burklow, John (NIH/OD) [E]  
 < (b) (6) Castillejos, Carlos < (b) (6) Culp, Michelle (NIH/OD) [E]  
 < (b) (6) FNIH Central Account < (b) (6) Freire, Maria (FNIH) [T]  
 < (b) (6) Gadbois, Ellen (NIH/OD) [E] < (b) (6) Hallett, Adrienne (NIH/OD) [E]  
 < (b) (6) Lane, Cliff (NIH/NIAID) [E] < (b) (6) Myles, Renate (NIH/OD) [E]  
 < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Tabak, Lawrence (NIH/OD) [E]  
 < (b) (6) Wolinetz, Carrie (NIH/OD) [E] < (b) (6) Burklow, John (NIH/OD) [E]  
 < (b) (6) Gorman, Greta (FNIH) [T] < (b) (6) Hallett, Adrienne (NIH/OD) [E]  
 < (b) (6) Meltzer, Abbey (FNIH) [T] < (b) (6) Myles, Renate (NIH/OD) [E]  
 < (b) (6) Wolinetz, Carrie (NIH/OD) [E] < (b) (6) Lucas Smalldon  
 < (b) (6) Villafana, Tonya < (b) (6) Brian Rosen  
 < (b) (6)

**Subject:** Materials for August 26 ACTIV Partnership Leadership Team Teleconference

**Importance:** High

Dear Colleagues:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from 3:00 – 4:00 PM Eastern U.S. time tomorrow, Wednesday August 26. (As a reminder, this meeting and future LT meetings are 60 minutes in length.) I have also attached notes from our July 29 Leadership Team meeting as well as our last ACTIV EC meeting on August 14.

The Zoom meeting information is:

Join Zoom Meeting

<https://fnih.zoom.us/>

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley  
Senior Vice-President, Research Partnerships

Foundation for the National Institutes of Health

(b) (6)

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**From:** Menetski, Joseph (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]

**Sent:** 6/3/2020 9:55:50 PM

**To:** (b) (6) (b) (6) (b) (6) (b) (6)  
 (b) (6) (b) (6) (b) (6) Baric, Ralph  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];  
 (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];  
 (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];  
 (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas /US [ (b) (6) Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [ (b) (6) Punturien, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]

**CC:** Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [ (b) (6) Hughes, Eric [ (b) (6) Jansen, Kathrin [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [ (b) (6) Kim, Elizabeth [ (b) (6) Tolman, Brett [ (b) (6) Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [ (b) (6) Diamond, Michael



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(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange  
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Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];  
Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi  
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=Sbbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D  
(b) (6) Dave Frankowski (b) (6) Lowy, Douglas (NIH/NCI) [E]  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowydl]; Florence, Clint (NIH/NIAID)  
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Louise Pitt  
(b) (6) (b) (6) Nancy Haigwood [/o=ExchangeLabs/ou=Exchange  
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Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]

**Subject:** ACTIV Preclinical working group (Friday meeting)

**Location:** <https://fnih.zoom>. (b) (6)

**Start:** 4/24/2020 3:00:00 PM

**End:** 4/24/2020 4:00:00 PM

**Show Time As:** Tentative

**Recurrence:** Weekly  
every Friday from 11:00 AM to 12:00 PM

**Required Attendees:** (b) (6) (b) (6) (b) (6) (b) (6)  
(b) (6) (b) (6) (b) (6) (b) (6)  
(b) (6) (b) (6) (b) (6) (b) (6);  
(b) (6) (b) (6) (b) (6) (b) (6)  
(b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];  
(b) (6) Adams, Peter (OS/ASPR/BARDA), Rao, Srinivas /US; Anderson, James (NIH/OD)  
[E]; Qashu, Felicia (NIH/OD) [E]; Tomas Cinlar; Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E];  
Fessel, Josh (NIH/NHLBI) [E]

**Optional Attendees:** Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine  
(NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Doug as  
(NCI), Read, Sarah (NIH/NIAID) [E], Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T];  
James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachter, Jonathan; Prabhavathi  
Fernandes; Diamond, Michael; Rose Li, Dana Carluccio, Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha  
(NIH/NCATS) [E], Gonzalez, Nina, Simon, Dina (NIH/OD) [C], Burrus-Shaw, Cyndi (NIH/OD) [E], Rodriguez, Robin D;  
Dave Frankowski, Lowy, Douglas (NIH/NCI) [E], Florence, Clint (NIH/NIAID) [E], Louise Pitt (b) (6)  
Nancy Haigwood, Hild, Sheri (NIH/OD) [E]

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**Sent:** 5/11/2020 2:08:33 PM  
**To:** Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Dolsten, Mikael [ (b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Pao, William [ (b) (6) Stoffels, Paul [ (b) (6) Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Corvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [ (b) (6) Hughes, Eric [ (b) (6) Jansen, Kathryn (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskiip]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]  
**CC:** Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Protasiewicz, Ann (b) (6) Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Zanellato, Ann [ (b) (6) Zottoli, Jessica [ (b) (6) Togashi, Mieko (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togash m]; Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]

**Subject:** ACTIV mtg with Exec Comm and WG co-chairs

**Location:** <https://fnih.zoom.us> (b) (6)

**Start:** 5/13/2020 12:00:00 PM

**End:** 5/13/2020 1:00:00 PM

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**Required Attendees:** Collins, Francis (NIH/OD) [E]; Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Pao, William; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Co vis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Wholey, David; Menetski, Joseph; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Freire, Maria (FNIH) [T]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]

**Optional Attendees:** Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C] McManus, Ayanna (NIH/OD) [E]; Protasiewicz, Ann; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Zanellato, Ann; Zottoli, Jessica; Togashi, Mieko (NIH/NCI) [E]; Sepulveda, Dorina (FNIH) [T]; Lagos, Enrique (NIH/NCATS) [E]; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]

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**Sent:** 5/22/2020 12:00:08 AM  
**To:** Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [ (b) (6) ]; LaVange, Lisa M [ (b) (6) ]; Sandeep Menon [ (b) (6) ]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [ (b) (6) ]; (b) (6) [ (b) (6) ]; (b) (6) [ (b) (6) ]; (b) (6) [ (b) (6) ]; Eron, Joe [ (b) (6) ]; Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; (b) (6) Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Jonathan Li [ (b) (6) ]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eedb7-Gilbert.Mar]; Kozak, Marina (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3881f41df744ad9dc3caa8f497a421-Marina.Koza]  
**CC:** Demarcus [ (b) (6) ]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [ (b) (6) ]; Elizabeth Kim [ (b) (6) ]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa [ (b) (6) ]; Eron, Joseph J Jr [ (b) (6) ]; Smith, David [ (b) (6) ]; Paul Klekotka [ (b) (6) ]; Ajay Nirula [ (b) (6) ]; Elsaid, Olivia [ (b) (6) ]; Robert Jan Benschoop [ (b) (6) ]; Lei Shen [ (b) (6) ]; Chen, Helen Q. [ (b) (6) ]  
**Subject:** Notes from the ACTIV TX-Clinical mAb Outpatient WT Meeting-3  
**Attachments:** ACTIV\_Therapeutics-Clinical\_ACTIV TX-Clinical mAb Outpatient WT Meeting-3\_20May2020\_Key Takeaways.pdf; Statistical Considerations - Proschan.docx

Dear ACTIV TX-Clinical mAb Outpatient WT,

Please find the notes from last night's writing team meeting for the group's reference. Please note the action items for follow up and the bolded text actions and decisions.

In addition, as requested, I am circulated the document of Statistical Considerations that Mike Proschan put together for ACTIV-1, the large Phase 3.

Thanks,  
Stacey

Stacey J. Adam, PhD  
Director, Cancer  
Research Partnership

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**From:** Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415B886087D08B628E6F-MELENCIOC]  
**Sent:** 7/21/2020 7:13:59 PM  
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 [ (b) (6) Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group  
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 [ (b) (6) Zottoli, Jessica [ (b) (6)

**Subject:** ACTIV EC & Working Group Co-Chair Meeting

**Location:** <https://nih.zoom.us/> (b) (6)

**Start:** 8/14/2020 7:30:00 PM

**End:** 8/14/2020 9:00:00 PM

**Show Time As:** Busy

**Required Attendees:** Collins, Francis (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA), Dolsten, Michael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Marks, Peter (FDA/CDER); Pao, William; Plump, Andrew; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurlla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John

**Optional Attendees:** Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olvia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Burklow, John (NIH/OD) [E]; Castillejos, Carlos; Culp, Michelle (NIH/OD) [E]; FNIH Central Account; Gadbois, El en (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Myles, Renate (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hardesty, Rebecca (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Gorman, Greta (FNIH) [T]; Meitzer, Abbey (FNIH) [T]; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Peralta, Mie; Protasiewicz, Ann; Riccobene, Kim; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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**From:** Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]  
**Sent:** 4/16/2020 12:13:10 AM  
**To:** Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy (b) (6) Hughes, Eric (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John (b) (6) Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]  
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**Subject:** FW: INPJTR REQUESTED by Friday, 9am ET: Vaccines Working Group Priorities  
**Flag:** Follow up

Dear Working Group Co-chairs and Francis,

The Vaccines Working Group members are providing input on the near-term priorities for the group. Your input would be welcome if you would like to **complete this survey by Friday, 9am ET:** <https://deloitte survey.deloitte.com/Community/se.ashx?s=3FC11B267EA61531>. It should take ~15 min. If you have any questions about the survey, please don't hesitate to reach out.

We will provide synthesis of the feedback ahead of the next Vaccines Working Group meeting, Monday, Apr 20 at 9am ET (6am PT / 2pm UK / 3pm CET); you should have already received a calendar invitation for that time.

Best regards,  
Mike, for the Vaccines Working Group

Michael Santos, PhD  
Associate Vice President, Science | Foundation for the National Institutes of Health

**From:** Santos, Michael (FNIH) [T]  
**Sent:** Wednesday, April 15, 2020 8:08 PM  
**Subject:** INPUT REQUESTED by Friday, 9am ET: Vaccines Working Group Priorities

Dear Vaccines Working Group Members,

Thank you for your participation in Monday's meeting. As we wrote below, the next step for our group is for you to provide input on the potential near-term (next 6 weeks) priorities for our working group.

**Please complete this survey by Friday, 9am ET:**

**<https://deloitteurvey.deloitte.com/Community/se.ashx?s=3FC11B267EA61531>**. It should take ~15 min. If you have any questions about the survey, please don't hesitate to reach out.

We will synthesize your feedback for a decision on immediate priority actions and next steps at our next working group meeting, Monday, Apr 20 at 9am ET (6am PT / 2pm UK / 3pm CET); you should have already received a calendar invitation for that time.

We are looking forward to your input.

Best regards,  
Mike, for the Vaccines Working Group

**Michael Santos, PhD**  
Associate Vice President, Science Foundation for the National Institutes of Health

**From:** Santos, Michael (FNIH) [T]  
**Sent:** Tuesday, April 14, 2020 11:42 AM  
**Subject:** Notes and Next Steps from the first meeting of ACTIV Vaccines Working Group

Dear Vaccines Working Group Members,

Thank you for your participation in yesterday's meeting. We appreciated your thoughtful comments and suggestions on the potential priorities for the working group.

Summary notes prepared by a science writer from Rose Li and Associates are attached; appendix B contains the Webex chat content. We will continue to circulate summaries like these the day after our meetings.

The key next step for our group is to prioritize the specific activities that we believe are worth taking on. Based on review of the proposals in our meeting by Kathrin and Doug, Brett and I will circulate a request to this group to give feedback on potential priorities. We will synthesize your input and provide it as a pre read ahead of our next Working Group meeting, which is being scheduled for next week.

Please continue to share your thoughts and suggestions on the best ways for this working group to support the global effort to develop and deliver Covid vaccines.

Best regards,  
Mike, for the Vaccines Working Group

**Michael Santos, PhD**  
Associate Vice President, Science Foundation for the National Institutes of Health

**From:** Santos, Michael (FNIH) [T]  
**Sent:** Sunday, April 12, 2020 12:25 PM  
**Subject:** Materials for first meeting of Covid PPP Vaccines Working Group: Tomorrow, April 13

Dear Vaccines Working Group Members,

We are looking forward to our first working group meeting tomorrow, April 13 at 9:30-11am ET (6:30am PT, 2:30pm UK, 3:30pm Western Europe). Materials for the meeting are attached:

- Meeting agenda: '2020-04-13 Vaccines Working Group meeting Agenda.docx'
- Meeting discussion topics: '2020-04-13 Vaccines Working Group meeting Key Topics For Discussion.docx'
- List of working group members and short bios: 'Vaccines Working Group Short Bios - 2020-04-13.pptx'

- In the interests of time, we will not be doing round-robin introductions at the start of the meeting, so please take advantage of the bios to familiarize yourself with the other members.
- For reference only: Notes from the Apr 3 meeting that launched our working group: 'FNIH Covid 19 meeting April 03 2020 notes.docx'

We know it is not possible for everyone to attend the meeting. **If you cannot attend, please send any input you would like represented in the meeting.** In addition, **we will be circulating notes after every meeting and invite additional comments on the discussion.**

One small logistical adjustment: the meeting platform will be Webex, and the meeting invite has been updated to reflect this. For your awareness, the co-chairs of the other 3 working groups (Christin Colvis, NIH and John Young, Roche; Eric Hughes, Novartis and Sarah Read, NIH; Betsy Desrosiers, Merck and Mike Kurilla, NIH) are invited to our meeting. A science writer and other members of the FNIH and Deloitte teams will also be on the line.

Please do not hesitate to reach out with any questions, concerns, or suggestions.

Best regards,  
Mike, for the Vaccines Working Group

Michael Santos, PhD  
Associate Vice President, Science | Foundation for the National Institutes of Health

**From:** Santos, Michael (FNIH) [T]  
**Sent:** Friday, April 10, 2020 7:26 PM  
**Subject:** First meeting of Covid PPP Vaccines Working Group: Monday, April 13

Dear Vaccines Working Group Members,

Thank you again for accepting Francis Collins' invitation to participate in the Covid Public-Private Partnership (PPP) Vaccines Working Group. This goal of this working group is to identify actions that we can take on collectively to accelerate R&D progress for vaccines to protect against Covid.

The **working group membership** is listed in the attached table. Kathrin Jansen of Pfizer and Doug Lowy of the US National Cancer Institute are the co-chairs, and Brett Tolman of Deloitte and I will be supporting the group. We are assembling a document with short bios of the group members to circulate to you, though we know that many of you know each other well already.

**Our first working group meeting is this Monday, April 13 at 9:30-11am ET (6:30am PT, 2pm UK, 3pm Western Europe);** a calendar invitation follows. We know it will not be possible for all members to make all meetings, especially with so much urgent work required every day. We will be distributing agendas ahead of meetings and notes afterwards, when you are not able to attend meetings, please send your input and we will incorporate it.

We will send materials for Monday's meeting over the weekend. We are looking forward to working with you to identify the opportunities for this group to add value and ensuring that we accomplish that. Please do not hesitate to reach out with any questions, concerns, or suggestions.

Best regards,  
Mike, for the Vaccines Working Group

Michael Santos, PhD  
Associate Vice President, Science  
Foundation for the National Institutes of Health  
(b) (6)      fnih.org

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**Sent:** 5/27/2020 12:53:21 AM

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**Subject:** Materials for ACTIV-2 Writing Team and mAb Steering Committee Joint Meeting

**Attachments:** ACTIV\_TX-Clinical\_ACTIV-2 Writing Team & mAb SteerCo Joint Meeting Agenda\_0527020.pdf; a5401-d06-052520v2.docx; Adapt Out COVID CSRC 052520.pdf

Dear ACTIV-2 Writing Team and ACTIV mAb Steering Committee,



We are looking forward to this joint meeting tomorrow in which the ACTIV-2 team will share their progress on the mAb outpatient master protocol with the Steering Committee. The team will review the current thinking within the protocol. Then they would like to solicit feedback from the Steering Committee about a few remaining questions that could still alter the protocol structure.

Please find attached the materials for tomorrow:

1. Meeting agenda
2. Current ACTIV-2 master protocol
3. Slides summarizing the current protocol

Please note that the stats team is still working to insert the final design of the Bayesian framework that will be used for agents beyond the first drug(s) into the trial for progression from Phase 2 to 3 within the study. This framework will not apply to the early entrants since prior learnings will be needed to inform the Bayesian model.

In addition, the team is waiting on some critical feedback from the FDA about how to address company feedback for a Phase 1(ish) safety/dose "run-in" study protocol that could be paired with the master protocol and potentially be overseen by ACTIV.

Thanks,  
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

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 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] (b) (6) Colvis, Christine (NIH/NCATS) [E] (b) (6) Hewitt, Judith (NIH/NIAD) [E] (b) (6) ; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; (b) (6) Rao, Srinivas (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [ (b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [ (b) (6) Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fessel.jp]; (b) (6) (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; (b) (6) (b) (6)

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg], Gonzalez, Nina  
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[ (b) (6) Dave Frankowski [ (b) (6) Lowy, Douglas (NIH/NCI) [E]  
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID)  
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[ (b) (6) Stratton, Benjamin [ (b) (6) Hughes, Eric  
[ (b) (6) Diamond, Michael [ (b) (6) Anderson, James (NIH/OD) [E]  
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**Attachments:** RE: ACTIV Preclin cal full working group

**Start:** 6/24/2020 2:00:00 PM

**End:** 6/24/2020 3:00:00 PM

**Recurrence:** (none)

**Required Attendees:** Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E]; (b) (6) (b) (6)  
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(b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];  
(b) (6) Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV  
USARMY MEDCOM USAMRIID (USA); Charette, Marc (NIH/NHLBI) [E], (b) (6) Punturier, Antone to  
(NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6) (b) (6)  
(b) (6) Adams, Peter (OS/ASPR/BARDA); (b) (6)  
**Optional Attendees:** Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine  
(NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read,  
Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James,  
Stephanie (FNIH) [T]; Alvarez, Rosa Maria, Kim, Elizabeth; Tolman, Brett; Wachter, Jonathan; Prabhavathi Fernandes;  
Rose Li; Dana Carluccio, Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon,  
Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Lowy, Douglas (NIH/NCI)  
[E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Gadbois, Ellen (NIH/OD) [E]; Nancy Haigwood; Baric, Toni C;  
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Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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**Subject:** RE: Follow-up Materials to ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5-Including New Score Sheet (Agents Added)  
**Attachments:** lancet respiratory medicine.pdf; Amgen - Otezla (Apremilast).pdf; Takeda - Takhzyro (Lanadelumab)- summary.pdf; Takeda - Firazyr (.catibant) -summary.pdf; Lilly-Taltz.pdf; BMS - Orencia (Apatcept).pdf; Allergan - Cenicriviroc.pdf

Hi All,

Finally, this is the third with the info sheets for the host targeted group.

Thanks,  
Stacey

Stacey J. Adam, PhD  
Director, Cancer  
Research Partnerships  
Direct: (b) (6) | Mobile: (b) (6)

**From:** Adam, Stacey (FNIH) [T]  
**Sent:** Thursday, April 30, 2020 7:05 PM

APAR0000005557-2517780

**Subject:** Follow-up Materials to ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5-Including New Score Sheet (Agents Added)

**Importance:** High

Dear TX-Clinical Agent Prioritization Subgroup,

I appreciate the candid and productive meeting that we had today. All your feedback is very helpful to refine our process for the next time.

For all of you working on scoring right now, please find attached a number of pieces of information that maybe helpful. Some if this some of your groups may have received before, however, I wanted to share it with the whole group for transparency and for having all of our reference data in one place. The information you will find attached is:

1. The summary spreadsheets for the agents in the host targeted category that have been added from the R&D Consortium group + 1 for Firazyr as it was requested. (one note, the group shared with us Firazyr is likely be tested in a few other trials, so that may need to be considered)
2. Articles on the evolving thrombosis issue that doctors are trying to deal with on the front lines. These were previously shared with the Symptomatic/Supportive therapy group.
3. An article relevant to immune modulator use in COVID-19.
4. Articles for the Antiviral group on some preclinical testing work.
5. Also for the antiviral group, the TX-Preclinical team also just sent this link with access to more screening data, which should contain all but EIDD-2801.
  - a. *"All of these compounds except EIDD-2801 are part of the ReFrame library and have been tested in a SARS-CoV-2 Vero-GFP CPE assay and posted at the ReFrame database here <https://reframedb.org/assays/A00440>. You can create an account for free and search the data."*

Please find attached the updated spreadsheet with all the new relevant compounds added for the groups to vote on. These new compounds for your groups are highlighted in green.

Finally, please find below the captured action items and key takeaways from the meeting

#### Action Items

Action Items		
	Information	POC
1	Provide Review Committee members with 5 compounds for review, along with factsheets from the R&D Consortium	Keith Gottesdiener & Elliott Levy /
2	Send updated score sheets Agent Prioritization Review Committee members (immunomodulators) score additional agents that have been added from the R&D Consortium list	Stacey Adam Stacey Adam
3	Getting standardized, reliable data on the agents	AP Sub Group Members
4	<ul style="list-style-type: none"><li>• Trans-NIH information, intramural and extramural</li></ul>	Stacey Adam / Ruxandra Draghia-Akli

- Mike Poole, Gates Foundation

5

Ask Preclinical Working Group (R&D members) for relevant data on agents if available

Joe Menetski

6

Get data on antivirals from NIAID and NCATS

Sarah Read/Christine Colvis

## Key Takeaways

- We are re-evaluating our list for scoring and adding other agents that were inadvertently left out
- We will not go back and re-evaluate the triage list.
- Sub Group Members voicing concern on lack of confidence in agents they've had to score. More research needed on drugs to understand whether these are worth putting into clinical trials. Need for more data.
- Suggested need to understand value of the agents we are evaluating over remdesivir.

For reference tomorrow, please find attached the summary from yesterday's meeting and the agenda for tomorrow's meeting.

Thanks,  
Stacey

Stacey J. Adam, PhD  
Director, Cancer  
Research Partnerships  
Foundation for the National Institutes of Health  
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**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
**Sent:** 5/1/2020 12:10:14 PM  
**To:** Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes [ (b) (6) ]; Read, Sarah (NIH/NIAID) [E] [ (b) (6) ]; Ruxandra Draghia-Akli [ (b) (6) ]; Mellors, John W [ (b) (6) ]; Naimish Patel [ (b) (6) ]; Colvis, Christine (NIH/NCATS) [E] [ (b) (6) ]; Young, John [ (b) (6) ]; Stein, Peter (FDA/CDER) [ (b) (6) ]; Poole, Mike [ (b) (6) ]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [ (b) (6) ]; Vincent, Michael [ (b) (6) ]; Keith Gottesdiener [ (b) (6) ]; Elliott Levy [ (b) (6) ]; Wung, Peter /US [ (b) (6) ]; Koroshetz, Walter (NIH/NINDS) [E] [ (b) (6) ]; Higgs, Elizabeth (NIH/NIAID) [E] [ (b) (6) ]; Carlos O Garner [ (b) (6) ];  
**CC:** Elizabeth Kim [ (b) (6) ]; Menetski, Joseph (FNIH) [T] [ (b) (6) ]; Salathin, Carla [ (b) (6) ]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [ (b) (6) ]; Melencio, Cheryl (FNIH) [T] [ (b) (6) ]; Lucas Smalldon [ (b) (6) ]; Walker, Paula (NIH/NINDS) [E] [ (b) (6) ]; Ward, Jackie (NIH/NINDS) [E] [jackie. (b) (6)];  
**Subject:** ACTIV Agent Prioritization Wave 1 Final Discussion Meeting  
**Attachments:** ACTIV Prioritization Criteria-2nd Stage Scoring Sheet-Wave 1-Tally.xlsx  
**Location:** <https://fnih.zoom>. (b) (6)

**Start:** 5/3/2020 7:00:00 PM  
**End:** 5/3/2020 8:00:00 PM  
**Show Time As:** Busy

**Required Attendees:** Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner  
**Optional Attendees:** Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Salathin, Carla; (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] (b) (6)

Hi ACTIV TX-Clinical Prioritization Subgroup members,

Please find attached the final tally of scores for the agents that came through triage in Wave 1. We will use this document for our discussions today.

For those who sent me comments, I did not want to overwhelm the score sheet with multiple rows of information. However, I have those and I will include them in the final record for posterity for this round. You can also feel free to bring them up during the discussion if helpful to the group.

Thanks,  
Stacey

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US (San Jose)

US (Tacoma)

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://fnih.zoom.us> (b) (6)

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**From:** Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C1B522-MYLESR]  
**Sent:** 4/16/2020 12:36:05 PM  
**To:** Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]  
**CC:** Wolinetz, Carne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]  
**Subject:** RE: PLEASE READ Draft Email to Collect Communication Contact Information

Unfortunately, I never received that list, but water under the bridge. It's been sent. Would you make sure to copy me on any updates to the list?

**From:** Parker, Ashley (NIH/OD) [E] < > (b) (6)  
**Sent:** Thursday, April 16, 2020 8:31 AM  
**To:** Myles, Renate (NIH/OD) [E] < > (b) (6)  
**Cc:** Wolinetz, Carrie (NIH/OD) [E] < > (b) (6)  
**Subject:** RE: PLEASE READ: Draft Email to Collect Communication Contact Information

The list was compiled yesterday morning by FNIH without any names, only emails. I wanted to double check the emails FNIH provided with names of the reps on the 4 ACTIV WGs along with the reps who participated in the April 3<sup>rd</sup> PPP meeting.

I found 8 emails that were missing and shared this with FC yesterday afternoon. Andy Plump was among the 8 which explains why his email was missing.

You now have the updated list – please let me know if you need anything else.

Ashley

**From:** Myles, Renate (NIH/OD) [E] < > (b) (6)  
**Sent:** Thursday, April 16, 2020 8:15 AM  
**To:** Parker, Ashley (NIH/OD) [E] < > (b) (6)  
**Cc:** Wolinetz, Carrie (NIH/OD) [E] < > (b) (6)  
**Subject:** RE: PLEASE READ: Draft Email to Collect Communication Contact Information

I used the master list that you sent to him earlier in the week and Takeda wasn't in there. I never received an updated version of the master list.

**From:** Parker, Ashley (NIH/OD) [E] < > (b) (6)  
**Sent:** Thursday, April 16, 2020 8:14 AM  
**To:** Myles, Renate (NIH/OD) [E] < > (b) (6)  
**Cc:** Wolinetz, Carrie (NIH/OD) [E] < > (b) (6)  
**Subject:** RE: PLEASE READ: Draft Email to Collect Communication Contact Information

Here is the updated list – seems FC used your emails and not the master list.

**From:** Myles, Renate (NIH/OD) [E] < > (b) (6)  
**Sent:** Thursday, April 16, 2020 8:10 AM  
**To:** Parker, Ashley (NIH/OD) [E] < > (b) (6)

**Cc:** Wolinetz, Carrie (NIH/OD) [E] <(b) (6)>  
**Subject:** RE: PLEASE READ: Draft Email to Collect Communication Contact Information

I pulled the names from the attached that you sent earlier in the week. There isn't a Takeda contact on this list. Would you send it to me?

**From:** Parker, Ashley (NIH/OD) [E] <(b) (6)>  
**Sent:** Thursday, April 16, 2020 8:03 AM  
**To:** Myles, Renate (NIH/OD) [E] (b) (6)  
**Cc:** Wolinetz, Carrie (NIH/OD) [E] (b) (6)  
**Subject:** RE: PLEASE READ: Draft Email to Collect Communication Contact Information

Good morning Renate,

Our rep at Takeda, Andy Plump is included on the master list. I am confirming with Francis that he used our master list for his email that went out last night – **I should be able to confirm this for you this morning.**

I hope you are staying safe and healthy; maybe even getting some rest in between the constant COVID activities.

Thanks,  
Ashley

**From:** Myles, Renate (NIH/OD) [E] <(b) (6)>  
**Sent:** Thursday, April 16, 2020 7:14 AM  
**To:** Parker, Ashley (NIH/OD) [E] (b) (6)  
**Cc:** Wolinetz, Carrie (NIH/OD) [E] (b) (6)  
**Subject:** FW: PLEASE READ: Draft Email to Collect Communication Contact Information  
**Importance:** High

Hi Ashley:

I'm not sure if Francis added a Takeda contact to his email. I could not find one on the master contact list. I have not heard from their organizations yet. Would you let me know if you provided that to him last night or if they are missing from this email? Need to send it to this group this morning.

Thanks,  
Renate

**From:** Myles, Renate (NIH/OD) [E]  
**Sent:** Wednesday, April 15, 2020 9:11 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6) >  
**Cc:** Wood, Gretchen (NIH/OD) [E] (b) (6) ; McManus, Ayanna (NIH/OD) [E]  
<(b) (6)> Burklow, John (NIH/OD) [E] (b) (6) <(b) (6)> Parker,  
Ashley (NIH/OD) [E] (b) (6)  
**Subject:** PLEASE READ: Draft Email to Collect Communication Contact Information  
**Importance:** High

Hi Francis:

We need to collect the communication contacts from the partner organizations so we can share the release with them for review. Below is 1) a draft email for you to send to the company participants, 2) the contacts for the companies we

list in the release except for Takeda (I could not find a Takeda contact on the master list; hoping Ashley can provide); 3) those who should be copied (feel free to add others).

Dear ACTIV colleagues:

As I mentioned earlier today, we would like to announce the plans for a public-private partnership as expeditiously as possible. Please provide the name of the most appropriate communication contact from your company so that we may share a draft of the embargoed press release for your review. Please send the contact information to Renate Myles at (b) (6) and Abbey Meltzer (b) (6) this evening, if possible.

BCC:

(b) (6)

CC:

(b) (6)

Thanks,  
Renate

**From:** Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]

**Sent:** 4/14/2020 10:48:29 PM

**To:** Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; (b) (6)

(b) (6) (b) (6) (b) (6) (b) (6)

(b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];

(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];

(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];

(b) (6) ; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas /US [ (b) (6) Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [ (b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]

**CC:** Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [ (b) (6) Hughes, Eric [ (b) (6) Jansen, Kathryn [ (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [ (b) (6) Kim, Elizabeth [ (b) (6) Tolman, Brett [ (b) (6) Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [ (b) (6) Diamond, Michael [ (b) (6) Rose Li [ (b) (6) Dana Carluccio





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**From:** Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]  
**Sent:** 7/8/2020 5:51:57 PM  
**To:** Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]  
**Subject:** RE: ACTIV Preclinical full working group

Thanks, Joe! Can you also please add me to the preclinical subgroup meetings?

Ashley

**From:** Menetski, Joseph (FNIH) [T] <(b) (6)>  
**Sent:** Wednesday, July 8, 2020 1:50 PM  
**To:** (b) (6) (b) (6) (b) (6) (b) (6) Hild, Sheri (NIH/OD) [E]  
<(b) (6)> (b) (6) (b) (6) (b) (6) (b) (6)  
(b) (6) (b) (6) (b) (6) Baric, Ralph <(b) (6)>  
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] <(b) (6)> Colvis, Christine  
(NIH/NCATS) [E] <(b) (6)> Hewitt, Judith (NIH/NIAID) [E] <(b) (6)> Deming, Damon  
(FDA/CDER) <(b) (6)> (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]  
<(b) (6)> (b) (6) Adams, Peter (OS/ASPR/BARDA)  
<(b) (6)> Rao, Srinivas <(b) (6)> Qashu, Felicia (NIH/OD) [E]  
<(b) (6)> Tomas Cihlar <(b) (6)> Pitt, Margaret L CIV USARMY MEDCOM USAMRIID  
(USA) <(b) (6)> Punturieri, Antonello (NIH/NHLBI) [E] <(b) (6)> Charette, Marc  
(NIH/NHLBI) [E] <(b) (6)> Fessel, Josh (NIH/NHLBI) [E] <(b) (6)>  
**Cc:** Diamond, Michael <(b) (6)> Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Florence,  
Clint (NIH/NIAID) [E] <(b) (6)> Simon, Dina (NIH/OD) [C] <(b) (6)> Wholley, David (FNIH)  
[T] <(b) (6)> Melencio, Cheryl (FNIH) [T] <(b) (6)> Colvis, Christine (NIH/NCATS) [E]  
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<(b) (6)> Jansen, Kathrin <(b) (6)> Kurilla, Michael (NIH/NCATS) [E]  
<(b) (6)> Lowy, Douglas (NCI) <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)>  
Tountas, Karen (FNIH) [T] <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Adam, Stacey (FNIH) [T]  
<(b) (6)> James, Stephanie (FNIH) [T] <(b) (6)> Alvarez, Rosa Maria <(b) (6)>  
Kim, Elizabeth <(b) (6)> Tolman, Brett <(b) (6)> Wachtel, Jonathan  
<(b) (6)> Prabhavathi Fernandes <(b) (6)> Rose Li  
<(b) (6)> Dana Carluccio <(b) (6)> Lagos, Enrique (NIH/NCATS) [E]  
<(b) (6)> Jonson, Samantha (NIH/NCATS) [E] <(b) (6)> Gonzalez, Nina  
<(b) (6)> Burrus-Shaw, Cyndi (NIH/OD) [E] <(b) (6)> Rodriguez, Robin D  
<(b) (6)> Dave Frankowski <(b) (6)> Baric, Toni C  
<(b) (6)> Lowy, Douglas (NIH/NCI) [E] <(b) (6)> Nancy Haigwood  
<(b) (6)> Stratton, Benjamin <(b) (6)> Gadbois, Ellen (NIH/OD) [E]  
<(b) (6)> Anderson, James (NIH/OD) [E] <(b) (6)>  
**Subject:** ACTIV Preclinical full working group

Dear Preclinical Working group and attendees,

I apologize for not providing the minutes from last week's meeting. Here they are for your review.

Sincerely,  
Joe

Joseph P. Menetski Ph.D.

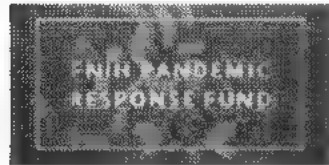
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**From:** Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]  
**Sent:** 11/20/2020 8:52:11 PM  
**To:** Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [ (b) (6) Eisner, Mark [ (b) (6) Gottesdiener, Keith (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [ (b) (6) LaVange, Lisa [ (b) (6) Levy, Elliot [ (b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras], Patel, Naimish (b) (6) Peppercorn, Amanda [ (b) (6) Poole, Mike [ (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia Colli]; Amanda Peppercorn [ (b) (6) Garner, Carl (b) (6) : Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dc8c847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [ (b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative

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CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy | (b) (6) Jansen, Kathrin | (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John (b) (6) Biggs, Mary | (b) (6) Butcher, Tina | (b) (6) Demarcus | (b) (6) Macone, Erin | (b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7248415bb86087d08b628e6f-melencioc]; Salathin, Carla | (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan (b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio | (b) (6) Rose Li Central Account | (b) (6) Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]. Lucas Smal don (b) (6) ]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188]; (b) (6) Mollica, Linda /US | (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, H lary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Wung, Peter /US | (b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) | (b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) | (b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acb5fd03bdfd32930-walkerp1]; Bethany Stokes | (b) (6) asorosa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]

**Subject:** Summary of ACTIV Therapeutics-Clinical Working Group Meeting

**Attachments:** 2020-11-19\_TX-Clinical\_WG\_Meeting\_Summary.pdf

Dear ACTIV TX-Clinical WG,

Please find attached the summary of yesterday's call. Per Novartis' request, we have excluded the summary of their presentation. We would like to thank them again for their attendance and willingness to review their data with us.

Thanks,  
Stacey

**Stacey J. Adam, PhD**

Director, Cancer

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(b) (6) Lowy, Douglas (NIH/NCI) [E] [ (b) (6) ]; (b) (6)  
Arvin, Ann [ (b) (6) Beth Bell ( (b) (6) [ (b) (6)  
susan. (b) (6) Cavaleri Marco (b) (6) (b) (6)  
(b) (6) Emil (b) (6) Greg Glenn [ (b) (6)  
(b) (6) Haynes, Barton [ (b) (6) (b) (6) (b) (6)  
Marks, Peter (FDA/CBER) [ (b) (6) Mascola, John (NIH/VRC) [E] [ (b) (6)  
Messonnier, Nancy (CDC/DDID/NCIRD/OD) [ (b) (6) Nelson Michael [ (b) (6)  
Offit, Paul [ (b) (6) Seals, Jonathan (OS/ASPR/BARDA) [Jonathan. (b) (6)  
(b) (6) (b) (6) Tal Zaks [ (b) (6) Collins, Francis  
(NIH/OD) [E] [ (b) (6) (b) (6)  
**CC:** Tolman, Brett [ (b) (6) ]; (b) (6) Hopps, Markay [ (b) (6)  
Kozlowski, Mary (NIH/NCI) [C] [mary. (b) (6) Johnson, Maureen (NIH/NCI) [E]  
[ (b) (6) nih.gov]; (b) (6) Jeneffer Haynes [ (b) (6)  
(b) (6) (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E]  
(b) (6) ; (b) (6) Isabel Ramsey [ (b) (6) Parker,  
Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Marston, Hilary  
(NIH/NIAID) [E] (b) (6) Qashu, Felicia (NIH/OD) [E] [ (b) (6) Culp, Michelle  
(NIH/OD) [E] [ (b) (6) Gadbois, Ellen (NIH/OD) [E] [ (b) (6) Wholley, David (FNIH) [T]  
(b) (6) ; Melencio, Cheryl (FNIH) [T] [ (b) (6) Menetski, Joseph (FNIH) [T]  
[ (b) (6) Adam, Stacey (FNIH) [T] [ (b) (6) Tountas, Karen (FNIH) [T] [ (b) (6)  
James, Stephanie (FNIH) [T] [ (b) (6) Colvis, Christine (NIH/NCATS) [E] [ (b) (6)  
Desrosiers, Betsy [ (b) (6) Hughes, Eric [ (b) (6) Kurilla, Michael  
(NIH/NCATS) [E] (b) (6) ; Read, Sarah (NIH/NIAID) [E] [ (b) (6) .gov]; Paul Gillard  
[ (b) (6) François P Roman [ (b) (6) Hamilton, Holli (OS/ASPR/BARDA)  
[ (b) (6) Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA)  
(b) (6) ; Kathleen Neuzil [ (b) (6) Schrag, Stephanie  
(CDC/DDID/NCIRD/DBD) [ (b) (6) Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) [ (b) (6)  
Thornburg, Natalie (CDC/DDID/NCIRD/DVD) [ (b) (6) Gonzalez, Nina [ (b) (6) 'Wachtel,  
Jonathan' [ (b) (6) Stratton, Benjamin [ (b) (6) rose.li@roseliassociates.com;  
(b) (6) Bethany Stokes [ (b) (6) Kathleen Callahan  
[ (b) (6) Arvin, Ann [ (b) (6) Wood, Gretchen (NIH/OD) [E]  
[ (b) (6) Young, John [ (b) (6) Anderson, Margaret  
[ (b) (6) Filip Dubovsky [ (b) (6)

**Subject:** ACTIV Vaccines Working Group meeting

**Location:** Webex: <https://nih.webex.com/join/join.aspx?room=joinurl> (b) (6)

**Start:** 7/29/2020 2:00:00 PM

**End:** 7/29/2020 3:00:00 PM

**Show Time As:** Tentative

**Required Attendees:** (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6) Arvin, Ann; Beth Bell  
(b) (6) (b) (6) Cavaleri Marco; (b) (6)  
(b) (6) (b) (6) Greg Glenn; (b) (6) Haynes,  
Barton; (b) (6) (b) (6) .ch; Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E];  
Messonnier, Nancy (CDC/DDID/NCIRD/OD); Nelson Michael; Offit, Paul; (b) (6) Seals, Jonathan  
(OS/ASPR/BARDA); (b) (6) (b) (6) ; Tal Zaks; Collins, Francis (NIH/OD)  
[E]



**Optional Attendees:** Tolman, Brett; (b) (6) Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen (NIH/NCI) [E]; (b) (6) Jeneffer Haynes; (b) (6) kel (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E]; (b) (6) Isabel Ramsey; Parker, Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul Gillard; François P Roman; Hamilton, Holli (OS/ASPR/BARDA); Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA); Kathleen Neuzil; Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin; Anderson, Margaret; (b) (6) (b) (6) Bethany Stokes; Kathleen Callahan; Ann Arvin; Wood, Gretchen (NIH/OD) [E]; Filip Dubovsky

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